THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

Mike Masiowski, M.D. on behalf of himself and all others similarly situated, Plaintiff, AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; McKESSON CORPORATION; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHOMCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ALLERGAN PLC f/k/a ACTAVIS PLS; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC. CVS HEALTH CORPORATION, THE KROGER COMPANY, WALGREENS BOOTS ALLIANCE, INC. WAL-MART, INC. ALPHA PHARMA SOLUTIONS, SMITH DRUG COMPANY, EXPRESS SCRIPTS, OPTUM. Defendants.	MDL 2804 CASE NO. 2:18-CV-2080 AMENDED CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

PLAINTIFF MICHAEL MASIOWSKI'S CORRECTED PROPOSED FIRST AMENDED CLASS ACTION COMPLAINT

Plaintiff, Michael Masiowski M. D. an emergency room physician, on behalf of himself and all others similarly situated, filed an action in the District of South Carolina, Charleston Division on July 25, 2018, and it was transferred to this Court on July 26, 2018 by the Judicial Panel on Multidistrict Litigation as Case 2:18-CV-2080.

Plaintiff, brings this Complaint against Defendants Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. McKesson Corporation; Cardinal Health, Inc.; Walmart, Inc., Walgreens Boots Alliance, Inc., Alpha Pharma Solutions, Smith Drug Company, The Kroger Company, CVS Health Corporation, Express Scripts Defendants, Optum Defendants, and AmerisourceBergen Drug Corporation (collectively "Defendants") and allege as follows:

(remainder of page intentionally left blank)

Table of Contents

INTRODUCTION

I. THE OPIOID CRISIS

1. This case is about one thing: corporate greed. Defendants put their desire for profits above the health and well-being of consumers, and emergency room physician health care providers at the cost to Plaintiff and the putative class of Independent Emergency Room Physicians[1] that he seeks to represent.

2. Independent Emergency Room Physicians is defined as those emergency room physicians that are non hospital employees and worked in emergency room as defined by EMTALA. It is estimated that approximately 77% of all Emergency Room Doctors are not hospital employees. [2]

3. Tens of thousands of patients have been treated by independent emergency room physicians because of the "opioid epidemic" throughout the United States.

4. Plaintiff and the putative class lost millions of dollars each year in providing emergency room health care services to patients who were opioid addicted, had opioid misuse issues, including "pill seeking", as well as those that were uninsured, were indigent (i.e. lacked resources to pay for the services), or otherwise eligible for services through programs such as Medicaid.

5. Medicaid payments were at below market rates. At times Plaintiff and the putative class were not compensated at all for services provided by uninsured patients. Additionally, Plaintiff and putative class were subjected patient satisfaction ratings and those ratings at times were

---

[1] Independent Emergency Room Physicians is defined as those emergency room physicians that are non hospital employees and worked in emergency room as defined by EMTALA.

[2] It is estimated that approximately 77% of all Emergency Room Doctors are not hospital employees. Carol K. Kane,PHD, "Policy Research Perspectives, Updated Data on Physician Practice Arrangements". American Medical Association, 2019.

negative from those denied opioids, impacting Plaintiff and putative classes wellbeing and reputations.

6. All of these services to be referred to as "Opioid Treatment Services" were necessary for Plaintiff and the putative class to provide because 1) regardless of whether a patient can pay, they must be provided medical care under prevailing federal and state law for medical and possible psychiatric care, and 2) of the adverse effects to patients from prescription opium painkillers ("opioids") which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants.

7. Independent Emergency Room Physicians across the United States are the front-line treatment for victims of the opioid epidemic. Independent Emergency Room Physicians are legally compelled to treat patients with opioid-related conditions and, as a result, have been directly damaged by the epidemic.[3] Plaintiff and the putative class, in essence, have been forced to provide an inordinate amount of emergency room services related to the "opioid epidemic," either for no compensation or for compensation substantially below market rates due to the unlawful marketing, distribution and sale of opioids. They have also been forced to spend time in training on accepted uses in order to renew necessary licenses or face loss of prescribing abilities.

8. Substance use disorders are a spectrum that range from misuse and abuse of drugs to addiction.[4] Throughout this Complaint, "addiction" refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder spectrum.

---

[3] Emergency Medical Treatment and Labor Act ("EMTALA"), 42 U.S.C. § 1395dd.

[4] Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) ("DSM-V").

9. Defendants knew that opioids were effective treatments for only short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care. Yet they also knew—and had known for years—that opioids were highly addictive and subject to abuse, particularly when used long- term for chronic non-cancer pain (pain lasting three months or longer, hereinafter referred to as "chronic pain"), and should there not be used except as a last-resort.

10. Defendants knew that, barring exceptional circumstances, opioids were too addictive and too debilitating for long-term use for chronic non-cancer pain lasting three months or longer.

11. Defendants further knew—and had known for years—that with prolonged use, the effectiveness of opioids wanes, requiring increases in doses and markedly increasing the risk of known significant side effects and addiction.[5,6]

12. Defendants also knew that controlled studies on the safety and efficacy of opioids were limited to short-term use (not longer than 90 days), and in managed settings (*e.g.*, hospitals), where the risk of addiction and other adverse outcomes was much less significant.

13. Indeed, the U.S. Food and Drug Administration ("FDA") has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.[7]

[5] *See, e.g.*, Russell K. Portenoy, Opioid Therapy for Chronic Nonmalignant Pain: Current Status, 1 Progress in Pain Res. & Mgmt. 247 (1994).

[6] The authoritative Diagnostic and Statistical Manual of Mental Disorders, (5th ed. 2013) ("DSM-V") "substance use disorders" are a spectrum that ranges from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on the substance use disorder continuum. Throughout this Complaint, "addiction" refers to this range of substance use disorders.

[7] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

14. According to the Centers for Disease Control ("CDC"), from 1999 to 2014, the sales of prescription opioids in the U.S. nearly quadrupled, but there was no overall change in the amount of pain that Americans reported.[8]

15. Prescription opioids, which include well-known brand-name drugs like OxyContin and Percocet, and generics like oxycodone and hydrocodone; are narcotics. They are derived from or possess properties similar to opium and heroin, which is why they are regulated as controlled substances.[9] Like heroin, prescription opioids work by binding to receptors on the spinal cord and in the brain, dampening the perception of pain. Opioids also can create a euphoric high, which can make them addictive. At certain doses, opioids can slow the user's breathing, causing respiratory depression and death.

16. Defendants' success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme supplies both ends of the secondary market for opioids—producing both the inventory of narcotics to sell and the addicts to buy them. One researcher who has closely studied the public health consequences of opioids has found, not surprisingly, that a "substantial increase in the nonmedical use of opioids is a predictable

---

[8] Centers for Disease Control and Prevention, *Prescribing Data*, *available at* https://www.cdc.gov/drugoverdose/data/prescribing.html, (last accessed April 30, 2018).

[9] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

adverse effect of substantial increases in the extent of prescriptive use."[10] It has been estimated that the majority of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

17. A significant black market in prescription opioids also has arisen, not only creating and supplying additional addicts, but fueling other criminal activities.

18. In addition, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Self-reported heroin use nearly doubled between 2007 and 2012, from 373,000 to 669,000 individuals. In 2010, more than 3,000 people in the U.S. died from heroin overdoses, also nearly double the rate in 2006. Nearly 80% of those who used heroin in the past year had previously abused prescription opioids. Patients become addicted to opioids and then move on to heroin because these prescription drugs are roughly four times more expensive than heroin on the street. In the words of one federal DEA official said , "Who would have ever thought in this country it would be cheaper to buy heroin than pills . . . [t]hat is the reality we're facing."[11]

19. According to the CDC, opioid overdoses killed more than 45,000 people in the 12 months that ended in September, 2017. It is already the deadliest drug epidemic in American history.[12] If trends continue, lost lives from opioid overdoses will soon represent the vast majority of all drug overdose deaths in the United States.

---

[10] G. Caleb Alexander et al., Rethinking Opioid Prescribing to Protect Patient Safety and Public Health, 308(18) JAMA 1865 (2012).

[11] Matt Pearce & Tina Susman, Philip Seymour Hoffman's death calls attention to rise in heroin use, L.A. Times, Feb. 3, 2014, http://articles.latimes.com/2014/feb/03/nation/la-na-heroin-surge-20140204 (accessed July 17, 2018).

[12] The Editorial Board, *An Opioid Crisis Foretold*, (Apr. 21, 2018), https://www.nytimes.com/2018/04/21/opinion/an-opioid-crisis-foretold.html.

20. Between the start of the century and the year 2014, opioid-related death rates increased by 200%. Fourteen percent of that increase occurred between 2013 and 2014.[13]

21. The opioid epidemic is killing scores of individuals each day, and having a similarly drastic impact on the total price tag for emergency room care provided by Independent Emergency Room Physicians. According to the CDC, the United States is currently seeing the highest overdose death rates ever recorded. [14] As opioid related deaths increase, the life expectancy in the United States has decreased.[15]

22. On October 28, 2017, the opioid crisis was declared a public health emergency.[16]

23. According to addiction programs, a typical course sees addicts requesting more and more opioids from their doctors, who eventually cut them off. Many addicts then doctor-shop for additional prescriptions, and when that source runs out, turn to the streets to buy opioids illicitly. A significant number become heroin addicts. Addiction treatment programs, whose patient populations vary, reported rates of patients who had switched from prescription opioids to heroin ranging from half to 95%. Those addicts who do reach treatment centers often do so when their health, jobs, families and relationships reach the breaking point, or after turning to criminal

[13] Id.

[14] Jessica Glenza, *Opioid crisis: overdoes increased by a third across US in 14 months, says CDC*, THE GUARDIAN (March 6, 2018), https://www.theguardian.com/us-news/2018/mar/06/opioid-crisis-overdoses-increased-by-a-third-across-us-in-14-months-says-cdc

[15] National Center for Health Statistics, Life Expectancy, *available at* https://www.cdc.gov/nchs/fastats/life-expectancy.htm, (last accessed April 30, 2018); Centers for Disease Control and Prevention, U.S. drug overdose deaths continue to rise; increase fueled by synthetic opioids, (March 18, 2018), https://www.cdc.gov/media/releases/2018/p0329-drug-overdose-deaths.html

[16] Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a 'Health Emergency' but Requests No* Funds, The New York Times (Oct. 26, 2017), https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html

activity such as prostitution and theft to sustain their addiction. Unfortunately, few are successful in getting and staying clean; repeated relapse is common.

24. From 2005 to 2014, emergency department visits exhibited a 99.4% cumulative increase.[17] The rate of opioid related emergency department visits nearly doubled. [18]

25. Independent Emergency Room Physicians directly bear the brunt of the opioid crisis. They are the main place most addicts and/or those with addiction related medical needs and issues will first seek care or attempt to obtain more opioids for their addiction. This was reasonably foreseeable by Defendants as a result of their actions and consequence to the opioid prescription epidemic. Defendants relied on Independent Emergency Room Physicians to mitigate the health consequences of their illegal activities. Defendants knew that but for Independent Emergency Room Physicians providing some safety net the number of overdose deaths and other related health issues would have been far greater.

26. In a 2021 survey of emergency physicians and professionals involved with billing for emergency department care, the most common response on the amount collected from uninsured patients for emergency physician professional services in 1,265 ED-Years for the period 2006-2021 was $21-$25. According to a May 2003 American Medical Association (AMA) study, emergency physicians annually incur, on average, $138,300 of EMTALA-related bad debt. Approximately 95.2% of emergency physicians provide some EMTALA mandated care in a

[17] Jennifer Bresnick, *Hospitals Face Higher Costs, More ED Visits from Opioid Abuse*, HealthIT Analytics (Dec. 21, 2016), https://healthitanalytics.com/news/hospitals-face-higher-costs-more-ed-visits-from-opioid-abuse, (last accessed on April 26, 2018).

[18] Audrey J. Weiss, et al, *Patient Characteristics of Opioid-Related Inpatient Stays and Emergency Department Visits Nationally and by State, 2014* (June 2017), https://www.hcup-us.ahrq.gov/reports/statbriefs/sb224-Patient-Characteristics-Opioid-Hospital-Stays-ED-Visits-by-State.pdf

typical week and more than one-third of emergency physicians provide more than 30 hours of EMTALA-related care each week and in many circumstances and, depending on the state in question, may not cover emergency physician costs for providing service.[19]

27. This suit takes aim at a primary cause of the opioid crisis: the actions of Defendants. In order to expand the market for opioids and realize blockbuster profits, Defendants, through the use of unfair and deceptive practices, created a sea of change in the medical and public perception that the use of opioids were not just safe and effective for acute and palliative care, but also safe for use for long periods to treat more common aches and pains, like lower back pain, arthritis, and headaches.

II. THE ROLE OF DEFENDANTS IN CAUSING AND PERPETUATING THE OPIOID CRISIS

28. The Manufacturing Defendants' goal was simple: to dramatically increase sales by convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer or short-term post-operative pain, but also for common chronic pains, such as back pain and arthritis. They did this even though they knew that opioids were addictive and subject to abuse, and that their other claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.

29. Distributor Defendants and National Retail Pharmacies Defendants—saw the profit potential in opioid sales, participated in the conspiracy by ignoring their legal responsibilities under

[19] American College of Emergency Physicians , The Impact of Unreimbursed Care on the Emergency Physician,. https://www.acep.org/administration/reimbursement/the-impact-of-unreimbursed-care-on-the-emergency-physician/

the Controlled Substance Act, and flooded affected areas with opioids well knowing they were contributing to, but profiting from, widespread addiction and human misery.

30. Manufacturing Defendants, through a sophisticated, highly deceptive and unfair marketing campaign that began in the late 1990s, which deepened around 2006, and continues to the present, set out to, and did, reverse the popular and medical understanding of opioids. Chronic opioid therapy—the prescribing of opioids to treat chronic pain long-term—is now commonplace.

31. To accomplish this, Defendants spent hundreds of millions of dollars:

a. developing and disseminating seemingly truthful scientific and educational materials and advertising that misrepresented the risks, benefits, and superiority of opioids long-term use to treat chronic pain;

b. deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the use of opioids;

c. recruiting prescribing physicians as paid speakers as a means to secure those physicians' future "brand loyalty" and extend their reach to all physicians;

d. funding, assisting, encouraging, and directing certain doctors, known as "key opinion leaders" ("KOLs"), not only to deliver scripted talks, but also to draft misleading studies, present continuing medical education programs ("CMEs") that were deceptive and lacked balance, and serve on the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy; and

e. funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups") that developed educational materials and treatment guidelines

that were then distributed by Defendants, which urged doctors to prescribe, and patients to use, opioids long-term to treat chronic pain.

32. These efforts, executed, developed, supported, and directed by Manufacturing Defendants, were designed not to present a fair view of how and when opioids could be safely and effectively used, but rather to convince doctors, patients, and others that the benefits of using opioids to treat chronic pain outweighed the risks and that opioids could be used safely by most patients. Defendants and the third parties whom they recruited and supported, all profited handsomely through their dissemination of the deceptive information. KOLs and Front Groups saw their stature in the medical community elevated dramatically due to Defendants' funding, and Defendants saw an equally dramatic rise in their revenues.

33. Working individually, with, and through these Front Groups and KOLs, Manufacturing Defendants pioneered a new and far broader market for their potent and highly addictive drugs—the chronic pain market. Defendants persuaded doctors, patients, and others that what they had long understood—that opioids are addictive drugs and unsafe in most circumstances for long-term use—was untrue, and to the contrary, that the compassionate treatment of pain *required* opioids. Ignoring the limitations and cautions in their own drugs' labels, Defendants:

a. overstated the benefits of chronic opioid therapy, promised improvement in patients' function and quality of life, and failed to disclose the lack of evidence supporting long-term use;

b. trivialized or obscured their serious risks and adverse outcomes, including the risk of addiction, overdose, and death;

c. overstated their superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives;

d. mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms. There was, and is, no competent or reliable scientific evidence to support Defendants' marketing claims, and there was, and is, a wealth of competent and reliable scientific evidence that these claims are simply false; and

e. deceptively and unfairly marketed the drugs for indications and benefits that were outside of the drugs' labels and not supported by substantial evidence.

34. Even Defendants' KOLs initially were very cautious about whether opioids were appropriate to treat chronic pain. Some of these same KOLs have since recanted their pro-opioid marketing messages and acknowledged that Defendants' marketing went too far. Yet despite the voices of renowned pain specialists, researchers, and physicians who have sounded the alarm on the overprescribing of opioids to treat chronic pain, Defendants continue to disseminate their misleading and unfair marketing claims to this day.

35. Defendants' efforts were wildly successful in expanding opioid abuse. The United States is now awash in opioids. In 2012, health care providers wrote 259 million prescriptions for opioid painkillers—enough to medicate every adult in America around the clock for a month. Twenty percent of all doctors' visits in 2010 resulted in the prescription of an opioid, nearly double the rate in 2000. Opioids—once a niche drug—are now the most prescribed class of drugs—more than blood pressure, cholesterol, or anxiety drugs. While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.

36. Together, opioids generated $8 billion in revenue for drug companies in 2012. Of that amount, $3.1 billion went to Non-Defendant Purdue for its OxyContin sales. By 2015, sales of opioids grew further to approximately $9.6 billion.[20]

37. It was Defendants' false marketing—and not any medical breakthrough—that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

38. Indeed, the National Institutes of Health ("NIH") not only recognizes the opioid abuse problem, but also identifies Defendants' "aggressive marketing" as a major cause: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies*."[21]

39. There is a direct correlation between the sales of opioids and deaths, emergency room treatment and hospitalizations caused by opioids:[22]

40. According to the U.S. Centers for Disease Control and Prevention ("CDC"), the nation has been swept up in an opioid-induced "public health epidemic."[23] The statistics are startling.

---

[20] D. Crow, Drugmakers hooked on $10bn opioid habit, Financial Times (August 10, 2016) available at https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95 (accessed July 17, 2018).

[21] America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse#_ftn2 (accessed July 12, 2018) (*emphasis added*).

[22] The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction, Annu. Rev. Public Health 2015, accessed at http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957 (accessed July 12, 2018)

[23] CDC, Examining the Growing Problems of Prescription Drug and Heroin Abuse (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm (accessed July 12, 2018)

Adult hospitalizations due to opioid misuse or dependence doubled from 2000 to 2012. From 2005 to 2014, emergency department visits exhibited a 99.4% cumulative increase.[24] According to the CDC, prescription opioid use contributed to 16,651 overdose deaths nationally in 2010; 16,917 in 2011; and 16,007 in 2012. One Defendant's own 2010 internal data shows that it knew that the use of prescription opioids gave rise to 40% of drug-related emergency department visits in 2010 and 40% of drug poisoning deaths in 2008, and that the trend of opioid poisonings was increasing from 1999-2008. For every death, more than 30 individuals are treated in emergency rooms.

41. According to the CDC, more than 12 million Americans age 12 or older have used prescription painkillers without a prescription in 2010, [25] and adolescents are abusing opioids in alarming numbers.

42. The average health care costs for opioid abusers were 8 times higher than those of non-abusers.[26]

43. Opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on the County and local agencies that address heroin use and addiction. According to the CDC, the percentage of heroin users who also use opioid pain relievers rose from 20.7% in 2002-2004 to 45.2% in 2011-2013. Heroin produces a very similar high to prescription opioids, but is often cheaper. While a single opioid pill may cost $10-$15 on the street,

---

[24] Jennifer Bresnick, *Hospitals Face Higher Costs, More ED Visits from Opioid Abuse*, HealthIT Analytics (Dec. 21, 2016), https://healthitanalytics.com/news/hospitals-face-higher-costs-more-ed-visits-from-opioid-abuse, (last accessed on April 26, 2018).

[25] CDC, Prescription Painkiller Overdoses in the US (Nov. 2011), https://www.cdc.gov/vitalsigns/painkilleroverdoses/ (accessed July 12, 2018).

[26] Alen G. White, PhD, et al., *Direct Costs of Opioid Abuse in an Insured Population in the United States*, published in Journal of Managed Care Pharmacy, Vol. 11, No. 6 July/August 2005, at 469.

users can obtain a bag of heroin, with multiple highs, for the same price. It is hard to imagine the powerful pull that would cause a law-abiding, middle-aged person who started on prescription opioids for a back injury to turn to buying, snorting, or injecting heroin, but that is the dark side of opioid abuse and addiction.

44. As a direct result of the opioid and eventual heroin epidemic more than 17,000 Americans died from prescription opioids in 2015 and the number continues to steadily grow.[27]

45. Statistics from the CDC found that in 2015, opioids were responsible for over 33,000 deaths nationwide.[28]

46. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct has caused and/or is continuing to cause a national, state, and local opioid epidemic.

47. Defendants' actions are not permitted or excused by the fact that their labels (with the exception of Cephalon's labels for Fentora and Actiq) may have allowed, or did not exclude, the use of opioids for chronic non-cancer pain. The FDA's approval did not give Defendants license to misrepresent the risks, benefits, or superiority of opioids. Indeed, what makes Defendants' efforts particularly nefarious—and dangerous—is that, unlike other prescription drugs marketed unlawfully in the past, opioids are highly addictive controlled substances. Defendants deceptively and unfairly engaged a patient base that—physically and psychologically—could not turn away from their drugs, many of whom were not helped by the drugs or were profoundly damaged by them.

---

[27] https://www.bloomberg.com/news/articles/2017-06-28/life-after-opioids-drugmakers-scramble-to-concoct-alternatives (accessed July 12, 2018)

[28] Executive Order 2017-146 (2017). Available at http://www.flgov.com/wp-content/uploads/orders/2017/EO_17-146.pdf (accessed July 12, 2018). *See also*, Executive Orders 2017-177 and 2017-230 (2017).

48. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were both ubiquitous and highly persuasive; their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants targeted not only pain specialists, but also primary care physicians (PCPs), nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess the companies' misleading statements. Defendants were also able to callously manipulate what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

49. As stated above, the National Institutes of Health ("NIH") not only recognizes the opioid abuse problem, but also identifies Defendants' "aggressive marketing" as a major cause.[29] As shown below, the "drastic increases in the number of prescriptions written and dispensed" and the "greater social acceptability for using medications for different purposes " are not really independent causative factors but are in fact the direct result of "the aggressive marketing by pharmaceutical companies."

50. The rising numbers of persons addicted to opioids have led to an increase in health care services that Plaintiff and the putative class he seeks to represent must provide for no compensation or below-market rate compensation.

51. The impacts of Defendants' conduct foreseeably include America's Emergency Room Departments and facilities. Under EMTALA, Independent Emergency Room Physicians are not only required to "provide medical screening examination for individuals" that visit the emergency

[29] America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2018/americas-addiction-to-opioids-heroin-prescription-drug-abuse (accessed July 12, 2018) (emphasis added).

department for any emergency medical condition, but also to provide treatment to stabilize the medical condition, or appropriately transfer the individual to another hospital. 42 U.S.C. §§ 1395dd (a) & (b). "In general any individual (whether or not eligible for benefits under this subchapter) comes to a hospital emergency room department and is treated by an Independent Emergency Room Physician and the Independent Emergency Room Physician determines that the individual has an emergency medical condition, they must provide either—(A) within the staff and facilities available at the hospital, for such further medical examination and such treatment as may be required to stabilize the medical condition, or (B) for transfer of the individual to another medical facility in accordance with subsection (c)." 42 U.S.C. § 1395dd (b).

52. Specifically Plaintiff, and the putative class he seeks to represent must deal with the consequences of a major increase in issues such as drug abuse, diversion,[30] and crimes related to obtaining opioid medications. Plaintiff and the putative class he seeks to represent have been severely and negatively impacted due to the fraudulent misrepresentations and omissions by Defendants regarding the use and risk related to opioids. In fact, upon information and belief, Defendants have been and continue to be aware of the high levels of diversion of their product.

53. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff and the putative class he seeks to represent have been required to provide millions of dollars of services for no compensation or substantially reduced compensation at below market rates. Plaintiff has incurred and continues to incur costs related to opioid addiction and abuse and misuse, including, but not limited to, substantial loss of appropriate compensation for increased emergency and medical care services and lost productivity and opportunity costs. Defendants' misrepresentations

[30] The CDC defines using or obtaining opioids illegally as "diversion."

regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff and the class that he seeks to represent.

54. As a direct and foreseeable consequence of Defendants' wrongful conduct Plaintiff and the putative class he seeks to represent had to obtain training on appropriate use of opioids and recognition of abuse for licensure causing Plaintiff and the putative class he seeks to represent incur monetary loss and also lost opportunity costs. Plaintiff and the class he seeks to represent were also damaged by being forced to consider patient satisfaction survey results or face negative employment consequences. These surveys asked patients how satisfied they were with treatment. If OUD patients were not given desired opioids, although physician felt they were drug seeking, at times they gave the physician a negative rating causing damage to the physician.

55. Opioid users have presented and continue to present themselves to Plaintiff claiming to have illnesses and medical problems, which are actually pretexts for obtaining opioids to satisfy their cravings. Plaintiff has incurred and continues to incur operational costs related to the time and expenses in diagnosing, testing, and otherwise dealing with "pill seekers" before their true status can be determined and they can be rejected as patients

56. Plaintiff has incurred and continues to incur substantial unreimbursed charges for its treatment of patients with opioid conditions. These patients with opioid-related conditions presented for treatment to Plaintiff as a proximate result of the opioid epidemic created and engineered by Defendants. As a result, Plaintiff's monetary losses with respect to treatment of these patients are foreseeable to Defendants and are the proximate result of Defendants' acts and omissions previously specified herein.

57. The Defendants have marketed and continue to market their opiate products directly to Plaintiff, and thus Plaintiff was and is a direct customer and victim of the Defendants' false, deceptive and unfair marketing of opioids described hereafter.

58. In sum, Plaintiff and the putative class that he seeks to represent have experienced economic costs directly related to the opioid epidemic, including substantial loss of income for having to provide emergency room medical services for either no compensation or payment substantially below market rates.

JURISDICTION AND VENUE

59. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* ("RICO"). This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

60. This Court independently has subject matter jurisdiction over Plaintiff's state law claims under 28 U.S.C. § 1332(d)(2)(A), because the matter in controversy, the aggregated claims of the individual Class members, exceeds the sum of five million dollars, exclusive of interest and costs, and Plaintiff is a citizen of a state different from Defendants. Under 28 U.S.C. §1332(d)(5), there are more than 100 members of the proposed class.

61. This Court has jurisdiction over this action pursuant to the provisions of S.C. Code § 36-2-803 in that Defendants, individually or acting by and through their authorized agents, officers, representatives, servants and employees, operated, conducted, transacted business in South Carolina; committed a tortious act within the state; caused tortious injury in the state; producing, manufacturing and/or distributing goods with the reasonable expectation that those

goods were to be used or consumed within the state, which were so used and consumed; by, among other things:

a. Manufacturing, selling and distributing highly addictive prescription opioid drugs in South Carolina while engaging in a pattern and practice of disseminating patently false and misleading information about the safety and efficacy of these opioid drugs;

b. Intentionally diminishing the associated health hazards of prescription opioid drugs and conspiring with key opinion leaders to increase their sales and profits despite the known risks and dangerous propensity of these drugs;

c. Consensually submitting to the jurisdiction of South Carolina when obtaining a manufacturer or distributor license; and/or

d. Owning and/or operating a distribution center in South Carolina that distributes the Defendant manufacturers' prescription opioid drugs to the citizens of South Carolina.

62. Defendants derived substantial revenue as the result of the opioids which were distributed to physicians, patients, and others and later consumed by persons then residing in the United States. Defendants' intentional and tortious conduct is continuing and presently existing, arose out of or is incidental to each Defendant's interstate, intrastate and international business ventures conducted in the United States, and proximately caused the Plaintiff to sustain losses and damages in the State of South Carolina, Ohio, and Georgia. Accordingly, the Defendants have the requisite minimum contacts with South Carolina necessary to constitutionally permit this Court to exercise jurisdiction because:

a. The Defendants' contacts with South Carolina, Ohio, and Georgia including, but not limited to, their manufacture, sale, distribution and/or promotion of highly addictive prescription opioid drugs, are directly related to and gave rise to this Complaint;

b. Defendants' purposefully availed themselves of the privilege of conducting business in South Carolina, Ohio, and Georgia by selling, distributing and/or promoting the use of highly addictive prescription opioid drugs to doctors, hospitals, patients, health insurers and other individuals throughout the South Carolina, Ohio, and Georgia, including, but not limited to Charleston County, South Carolina;Dorchester County, South Carolina; Aiken County, South Carolina; Orangeburg County, South Carolina; Allendale County, South Carolina; Richland County, South Carolina; Berkley County, South Carolina; Shelby County, Ohio; Burke County, Georgia, and Douglas County, Georgia; ; and,

c. Defendants' fraudulent and deceptive marketing campaign and intentional misconduct was such that the Defendants should have reasonably anticipated being hauled into court.

63. Venue is proper in this District under 28 U.S.C. § 1391(b)(2), because Plaintiff is domiciled in this judicial district, because a substantial part of the events and omissions giving rise to Plaintiff's claims occurred in this judicial district, and under 28 U.S.C. § 1391 (b)(1) and § (c)(2), because all the Defendants are subject to personal jurisdiction in this state and in this judicial district, such that Defendants are deemed to reside in this state and in this judicial district.

PARTIES

I. PLAINTIFF

64. Plaintiff, has been an independent emergency room physician who independently practiced in Dorchester County, SC., Berkley County, SC., Charleston County, SC., Allendale County, SC., Richland County, SC., Aiken County, SC., Orangeburg County, SC., Shelby County, OH., Burke County, GA., and Douglas County, GA for the relevant timeframe herein.

II. DEFENDANTS

A. Manufacturer Defendants[31]

65. The Manufacturing Defendants' push to increase opioid sales worked. Through their publications and websites, endless stream of sales representatives, "education" programs, and other means, Manufacturing Defendants dramatically increased their sales of prescription opioids and reaped billions of dollars of profit as a result. Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled. In 2016, 289 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month.

66. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors, and pharmacies, who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know should be necessary for

[31] Cephalon and Associated Companies, Janssen and Associated Companies, Non-Defendant Endo and Associated Companies, Non Defendant Insys Therapeutics, Purdue, Non Defendant Mallinckrodt Entities, Actavis and Associated Companies, Teva Pharmaceuticals, and Aphena Pharma Solutions.

legitimate medical uses, while failing to report, and to take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

67. From the day they made the pills to the day those pills were consumed in each community, these manufacturers had control over the information regarding addiction they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring them into prescribing their products by arguing, among other things, that no one should be in pain, the Manufacturer Defendants created a population of addicted patients who sought opioids at never-before-seen rates. The scheme worked, and through it the Manufacturer Defendants caused their profits to soar as more and more people became dependent on opioids.

68. Opioid manufacturing and distributing companies systematically and repeatedly disregarded the health and safety of their customers and the public. Charged by law to monitor and report dangerous behavior, they failed to do so in favor of maximizing corporate profits and increasing their market share.

69. The Manufacturer Defendants falsely and misleadingly, and contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudo addiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; (6) promoted the falsehood that long term opioid use improves functioning; (7) misrepresented the effectiveness of time-released dosing, and, in particular, the effectiveness of a version of OxyContin

that purportedly provided twelve hours of pain relief; and (8) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction.

70. The Manufacturer Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians who were recruited by and paid by the Manufacturer Defendants for their support of the Manufacturer Defendants' marketing messages.

71. The Manufacturer Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) creating, funding, assisting, directing, and/or encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). The Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Manufacturer Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

72. Each Manufacturer Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug

Administration ("FDA") and the CDC, including by CDC's *Guideline for Prescribing Opioids for Chronic Pain*, issued in 2016 and approved by the FDA.[32]

73. In an open letter to the nation's physicians in August 2016, the then U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[33]

74. The Manufacturer Defendants are listed below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty prevent diversion and report suspicious orders.

75. Purdue manufactures, promotes, sells, and distributes opioids in the United States and South Carolina, including the following:

a. OxyContin (oxycodone hydrochloride extended release) is a Schedule II opioid agonist[34] tablet first approved in 1995 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment

[32] *See* Centers for Disease Control and Prevention, *Guideline for Prescribing Opioids For Chronic Pain*, https://www.cdc.gov/drugoverdose/pdf/guidelines factsheet-a.pdf (last accessed April 12, 2018); Pat Anson, *FDA Endorses CDC Opioid Guidelines*, PAIN NEWS NETWORK (Feb. 4, 2016), https://www.painnewsnetwork.org/stories/2016/2/4/fda-endorses-cdc-opioid-guidelines

[33] Letter from Vivek H. Murthy, M.D., U.S. Surgeon General, *available at* http://turnthetiderx.org/ (last accessed April 12, 2018).

[34] An opioid agonist is a drug that activates certain opioid receptors in the brain. An antagonist, by contrast, blocks the receptor and can also be used in pain relief or to counter the effect of an opioid overdose.

and for which alternative treatment options are inadequate." Prior to April 2014,[35] OxyContin was indicated for the "management of moderate to severe pain when a continuous, around-the- clock opioid analgesic is needed for an extended period of time."

b. MS Contin (morphine sulfate extended release) is a Schedule II opioid agonist tablet first approved in 1987 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, MS Contin was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

c. Dilaudid (hydromorphone hydrochloride) is a Schedule II opioid agonist first approved in 1984 (injection) and 1992 (oral solution and tablet) and indicated for the "management of pain in patients where an opioid analgesic is appropriate."

d. Dilaudid-HP (hydromorphone hydrochloride) is a Schedule II opioid agonist injection first approved in 1984 and indicated for the "relief of moderate-to-severe pain in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief."

[35] The labels for OxyContin and other long-acting opioids were amended in response to a 2012 citizens' petition by doctors. The changes were intended to clarify the existing obligation to "make an individualized assessment of patient needs." The petitioners also successfully urged that the revised labels heighten the requirements for boxed label warnings related to addiction, abuse, and misuse by changing "Monitor for signs of misuse, abuse, and addiction" to "[Drug name] exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death." Letter from Bob Rappaport, Dir. Ctr. for Drug Evaluations & Res., Labeling Supplement and PMR [Post-Marketing Research] Required (Sept. 10, 2013), http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf (accessed July 12, 2018).

e. Butrans (buprenorphine) is a Schedule III opioid partial agonist transdermal patch first approved in 2010 and indicated for the "management of pain severe enough to require daily, around- the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Butrans was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

f. Hysingla ER (hydrocodone bitrate) is a Schedule II opioid agonist tablet first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

g. Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) is a Schedule II combination product of oxycodone, an opioid agonist, and naloxone, an opioid antagonist, first approved in 2014 and indicated for the management of pain severe enough to require daily, around- the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

76. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

77. Purdue is included herein to assist with the illustration of the history of the opioid abuse and misuse problem and the common scheme all the Manufacturing Defendants engaged in. The Manufacturing Defendants engaged in actions that also substantially contributed to the Opioid epidemic.

78. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

79. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petach Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation which is a wholly owned subsidiary of Teva Ltd. In Pennsylvania. Teva USA acquired Cephalon in October of 2011.

80. Cephalon has been in the business of manufacturing, selling, and distributing the following opioids, in the United States and South Carolina:

a. Actiq (fentanyl citrate) is a Schedule II opioid agonist lozenge (lollipop) first approved in 1998 and indicated for the “management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.”

b. Fentora (fentanyl citrate) is a Schedule II opioid agonist buccal tablet (similar to plugs of smokeless tobacco) first approved in 2006 and indicated for the “management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”

81. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million.[36]

[36] Press Release, U.S. . Dep't of Justice, Biopharmaceutical Company. Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008),

82. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October of 2011 acquisition of Cephal on. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

83. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[37] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 - the year immediately following the Cephalon acquisition- attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including *inter alia* sales of Fentora®.[38] Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as

---

https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html (last accessed Jul. 12, 2018).

[37] *E.g.,* ACTIQ, http://www.actiq.com/ (displaying logo at bottom-left) (accessed July 12, 2018).

[38] Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf (accessed July 13, 2018)

controlling shareholder. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon."

84. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. NORAMCO, INC. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July of 2016. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco, and J&J are referred to as "Janssen."

85. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales.

86. Until January 2015, Janssen developed, marketed, and sold the following opioids in the United States and South Carolina:

a. Nucynta ER (tapentadol extended release) is a Schedule II opioid agonist tablet first approved in 2011 and indicated for the “management of pain severe enough to

require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Nucynta ER was indicated for the "management of moderate to severe chronic pain in adults [and] neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults." The DPN indication was added in August 2012.

b. Nucynta (tapentadol) is a Schedule II opioid agonist tablet and oral solution first approved in 2008 and indicated for the "relief of moderate to severe acute pain in patients 18 years of age or older."

c. Janssen (Noramco) sold the majority of its controlled substance through long term agreements and had such agreements with all 7 of the top U. S. generic drug companies. [39] It also grew to become the No. 1 narcotic API supplier of oxycodone, hydrocodone, codeine and morphine in the US. Id.

d. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

87. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTA VIS PLC acquired ALLERGAN PLC in March 2015, and the combined company changed its name to ALLERGAN PLC in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then ACTAVIS PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly

[39] State of Oklahoma v. Purdue, Case No. CJ-2017-816 Judge Balkman's decision filed 8/26/10/19 para 14 findings of fact.

known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by ALLERGAN PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, ALLERGAN PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/ Actavis products ultimately inure to its benefit. ALLERGAN PLC, ACTAVIS PLC, ACTAVIS, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis."

88. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States and South Carolina. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

89. APHENA PHARMA SOLUTIONS is a contract pharmaceutical manufacturing and packaging company that serves the pharmaceutical industry from two distinct operations in the United States — a solid-dose division in Tennessee and a liquid manufacturing and packaging campus in Maryland — both of which are both DEA licensed and FDA registered. Aphena Pharma Solutions was originally formed by established contract pharmaceutical companies: PrePak, TestPak, Celeste, and Integrated Pharmaceutical Packaging. Their alliance is now called Aphena Pharma Solutions. Aphena Pharma Solutions maintained a Pharmaceutical/Distributor Market Share of 10.67% Charleston County S.C., from 2006 through 2019. Plaintiff Masiowski practiced as an Emergency Room Physician in Charleston County S.C. intermittently during this period.

C. Distributor Defendants[40]

90. The Distributor Defendants are identified below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing the United States.

91. McKESSON CORPORATION ("McKesson") is a Delaware corporation, with its principal place of business located in San Francisco, California. McKesson distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states including South Carolina.

92. McKesson is the largest pharmaceutical distributor in North America. McKesson delivers approximately one-third of all pharmaceuticals used in North America

93. For fiscal year ended March 31, 2017, McKesson generated revenues of $198.5 billion.

94. In its 2017 Annual Report, McKesson states that it "partner[s] with pharmaceutical manufacturers, providers, pharmacies, governments and other organizations in healthcare to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively."[41]

---

[40] McKesson Corporation, Cardinal, AmerisourceBergen Drug Corporation, Walmart Inc., Walgreens Boot Alliance/Walgreens Co., Smith Drug Comopany.

[41] McKesson, Annual Report, http://investor.mckesson.com/sites/mckesson.investorhq.businesswire.com/files/report/file/2017 McKess on Annual Report 0.pdf (last accessed April 12, 2018).

95. According to the 2017 Annual Report, McKesson's "pharmaceutical distribution business operates and serves thousands of customer locations through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico."

96. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country.

97. In January 2017, McKesson paid a record $150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan and Colorado. The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."

98. McKesson is the largest pharmaceutical distributor in the United States

99. CARDINAL HEALTH, INC. ("Cardinal") is an Ohio corporation with its principal place of business located in Dublin, Ohio. Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states including South Carolina.

100. Cardinal is a global distributor of pharmaceutical drugs and medical products. It is one of the largest distributors of opioids in the United States. It has annual resources of over $120 billion. Additionally, in December 2013, Cardinal formed a ten-year agreement with CVS Caremark to form the largest generic drug sourcing operation in the United States. Cardinal has, at all relevant times, had distribution centers throughout the United States, including S. Carolina, and has distributed opioids nationwide.

101. AMERISOURCEBERGEN DRUG CORPORATION ("AmerisourceBergen") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. AmerisourceBergen distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states including South Carolina.

102. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care."[42]

103. Collectively, McKesson, AmerisourceBergen, and Cardinal account for 85% of the drug shipments in the United States. These companies together collect about $400 billion in annual revenue.

104. SMITH DRUG COMPANY is a full-line wholesale pharmacy distribution company serving independent community and long-term care pharmacies. It is based in Spartanburg, SC. Smith Drug Company utilizes electronic ordering and signing (CSOS) for ordering controlled substances. Their systems allow pharmacies to order and sign electronically, while complying with DEA guidelines. Smith Drug Company maintained a Pharmaceutical/Distributor Market Share of 5% or greater in Allendale County S.C., Aiken County S.C., Orangeburg County, S.C., Douglas County S.C., Burke County S.C., from 2006 through 2019. Plaintiff Masiowski practiced as an Emergency Room Physician in all of these counties intermittently during this period.

105. WALGREENS BOOT ALLIANCE (WBA) is an American multinational holding company headquartered in Deerfield, Illinois, which owns the retail pharmacy chains Walgreens

---

[42] AmerisourceBergen, 2016 Summary Annual Report, http://investor.amerisourcebergen.com/static-files/37daf1ed-4d41-4547-bb87-86d501087dbb (last accessed April 12, 2018

in the US and Boots in the UK, as well as several pharmaceutical manufacturing and distribution companies. Walgreen Co. ("Walgreens") is a Delaware corporation with its principal place of business in Illinois. At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including S. Carolina. Defendant Walgreens maintained a Pharmaceutical/Distributor Market Share of 5% or greater in Berkley County, S.C., Orangeburg County S.C., Richland County S.C., Shelby County OH, Burke County GA.., from 2006 through 2019. Plaintiff Masiowski practiced as an Emergency Room Physician in all of these counties intermittently during this period.

106. The WALMART Pharmacy distribution network includes *a network of Walmart owned pharmacy distribution centers* located across the U.S. Wal-Mart Inc., formerly known as Wal-Mart Stores, Inc. ("Wal-Mart"), is a Delaware corporation with its principal place of business in Arkansas. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States, including S. Carolina. Wal-Mart maintained a Pharmaceutical/Distributor Market Share of 5% or greater in Dorchester County, S.C., Berkley County S.C., Aiken County S.C., Orangeburg County, S.C., Richland County S.C., Shelby County OH., Burke County GA., from 2006 through 2019. Plaintiff Masiowski practiced as an Emergency Room Physician in all of these counties intermittently during this period.

D. National Retail Pharmacy Defendants

107. At all relevant times, the National Retail Pharmacy Defendants have distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of a pharmacy to detect and warn of diversion of dangerous drugs for non-medical

purposes. The National Retail Pharmacy Defendants universally failed to comply with federal law. Plaintiff alleges the unlawful conduct by the National Retail Pharmacy Defendants is responsible for the volume of prescription opioids plaguing the United States.

108. CVS HEALTH CORPORATION ("CVS") is a Delaware corporation with its principal place of business in Rhode Island. At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States, including S. Carolina. CVS maintained a Pharmaceutical/Distributor Market Share of 5% or greater in Dorchester County, S.C., Berkley County S.C., Aiken County S.C., Orangeburg County, S.C., Richland County S.C., Shelby County SOH., Douglas County GA., Burke County GA., from 2006 through 2019. Plaintiff Masiowski practiced as an Emergency Room Physician in all of these counties intermittently during this period.

109. THE KROGER CO. ("Kroger) is an Ohio corporation with headquarters in Cincinnati, OH. Kroger operates more than 2,000 pharmacies in the United States, including in Ohio. At all times relevant to this Complaint, Kroger distributed prescription opioids throughout the United States, including in Shelby County, Ohio, a County where Plaintiff Masiowski practiced as an Independent Emergency Room Physician. From 2006 through 2019, Kroger maintained a 5.53% Market Share.

110. WALGREENS BOOT ALLIANCE (WBA) is an American multinational holding company headquartered in Deerfield, Illinois, which owns the retail pharmacy chains Walgreens in the US and Boots in the UK, as well as several pharmaceutical manufacturing and distribution companies. Walgreen Co. ("Walgreens") is a Delaware corporation with its principal place of business in Illinois. At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including S. Carolina. Defendant Walgreens maintained a

Pharmaceutical/Distributor Market Share of 5% or greater in Berlkey County, S.C., Orangeburg County S.C., Richland County S.C., Shelby County OH., Burke County GA., from 2006 through 2019. Plaintiff Masiowski practiced as an Emergency Room Physician in all of these counties intermittently during this period.

111. WALMART, INC., formerly known as Wal-Mart Stores, Inc. ("Wal-Mart"), is a Delaware corporation with its principal place of business in Arkansas. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States, including S. Carolina. Wal-Mart maintained a Pharmaceutical/Distributor Market Share of 5% or greater in Dorchester County, S.C., Berkley County S.C., Aiken County S.C., Orangeburg County, S.C., Richland County S.C., Shelby County OH., Burke County SGA., from 2006 through 2019. Plaintiff Masiowski practiced as an Emergency Room Physician in all of these counties intermittently during this period.

E. PBM Defendants

112. The Express Scripts Defendants

a. **Defendant Evernorth Health, Inc.** (f/k/a Express Scripts Holding Company) ("Evernorth") is a Delaware corporation Evernorth Health, Inc.'s principal place of business is at 1 Express Way, St. Louis, Missouri 63121.

b. Evernorth is the parent company to all of the Express Scripts entities named as Defendants. Evernorth, through its executives and employees, controls the enterprise-wide policies that inform all of Express Scripts' lines of business in order to maximize profits across the corporate family.

c. Evernorth's conduct had a direct effect in New York, including Plaintiff's Community.

d. **Defendant Express Scripts, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc. Express Scripts, Inc.'s principal place of business is at 1 Express Way, St. Louis, Missouri 63121.

e. Express Scripts, Inc. is the immediate or indirect parent of pharmacy and PBM subsidiaries that operate throughout New York that engaged in the conduct which gives rise to this Complaint.

f. During the relevant time period, Express Scripts Inc. was directly involved in the PBM and mail order services businesses, including with respect to the at-issue drugs, as well as Express Scripts' data and research services.

g. **Defendant Express Scripts Administrators, LLC**, is a Delaware limited liability company and is a wholly owned subsidiary of Evernorth Health, Inc. Express Scripts Administrators, LLC's principal place of business is at the same location as Express Scripts, Inc.

h. Express Scripts Administrators, LLC is registered to do business in New York and may be served through its registered agent CT Corporation System, 28 Liberty Street, New York, NY 10005.

i. During the relevant time period, Express Scripts Administrators, LLC provided and/or offered PBM services in New York, including Plaintiff's Community, alleged in this complaint.

j. **Defendant Medco Health Solutions, Inc.** (f/k/a Merck-Medco) ("Medco") is a Delaware Corporation with its principal place of business located at 100 Parsons Pond Road, Franklin Lakes, New Jersey, and is a wholly-owned subsidiary of Evernorth Health, Inc. Medco Health Solutions, Inc. was previously known as

Merck-Medco. Merck-Medco was acquired in the early 1990s by Merck & Co. as its pharmacy benefit manager subsidiary. In 2002, Merck & Co. spun off Merck-Medco into a publicly traded company, defendant Medco Health Solutions, Inc.

k. Medco Health Solutions, Inc. is registered to do business in New York and may be served through its registered agent: CT Corporation Syste, 28 Liberty Street, New York, NY 10005.

l. **Defendant ESI Mail Order Processing, Inc**. is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc.

m. During the relevant time period, ESI Mail Order Processing, Inc. provided and/or offered mail order pharmacy services in New York, including Plaintiff's Community, alleged in this Complaint, which gives rise to the causes of action herein.

n. **Defendant ESI Mail Pharmacy Service, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc. ESI Mail Pharmacy Service, Inc.'s principal place of business is at the same location as Express Scripts, Inc.

o. ESI Mail Pharmacy Service, Inc. d/b/a Express Scripts, Inc., does business in New York and may be served through Express Scripts' registered agent: CT Corporation System, 28 Liberty Street, New York, NY 10005.

p. During the relevant time period, ESI Mail Pharmacy Service provided mail order pharmacy services in New York, including Plaintiff's Community, as alleged in this Complaint, which gives rise to the causes of action herein.

q. **Defendant Express Scripts Pharmacy, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc. Express Scripts Pharmacy, Inc.'s principal place of business is at the same location as Express Scripts, Inc.

r. Express Scripts Pharmacy, Inc. is registered to do business in New York and may be served through its registered agent: CT Corporation System, 28 Liberty Street, New York, NY 10005.

s. Express Scripts Pharmacy, Inc. holds active licenses with the New York State Board of Pharmacy.

t. During the relevant time period, Express Scripts Pharmacy, Inc. provided and/or offered mail order pharmacy services in New York, including Plaintiff's Community, alleged in this Complaint, which gives rise to the causes of action herein.

u. Express Scripts Pharmacy, Inc. and ESI Mail Pharmacy Service, Inc. are referred to herein collectively as "Express Scripts Mail Order Pharmacy."

v. In 2021, Express Scripts Mail Order Pharmacy was the third largest dispensing pharmacy in the United States and reported $54.4 billion in prescription revenues.

w. From 2006 to 2014, Express Scripts Mail Order Pharmacy bought over 22.9 billion MMEs of opioids spread over 1.1 billion opioid dosage units.

x. **Defendant Express Scripts Specialty Distribution Services, Inc.** is a Delaware corporation and is a wholly owned subsidiary of Evernorth Health, Inc. Express Scripts Specialty Distribution Services, Inc.'s principal place of business is at the same location as Express Scripts, Inc.

y. During the relevant time period, as alleged in more detail herein, Express Scripts Specialty Distribution Services, Inc. worked directly with the opioid manufacturers to expand the opioid market, including with Purdue to administer and dispense opioids through these opioid manufacturers' Patient Assistance Programs, including in New York.

z. Collectively, Defendants Evernorth Health, Inc., Express Scripts, Inc., Express Scripts Administrators, LLC, Medco Health Solutions, Inc., ESI Mail Order Processing, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc., and Express Scripts Specialty Distribution Services, Inc., including all predecessor and successor entities, are referred to as "Express Scripts" or "ESI."

aa. Express Scripts is named as a Defendant in its capacities as a: (1) PBM; (2) data, analytics, and research provider; and (3) mail order pharmacy. During the relevant time period, Express Scripts contracted directly with the opioid manufacturers in each of these capacities. At all relevant times, Express Scripts performed these services in New York and Plaintiff's Community.

bb. In 2019, Express Scripts merged with Cigna, Inc. Prior to merging with Cigna, Express Scripts was the largest independent PBM in the United States.

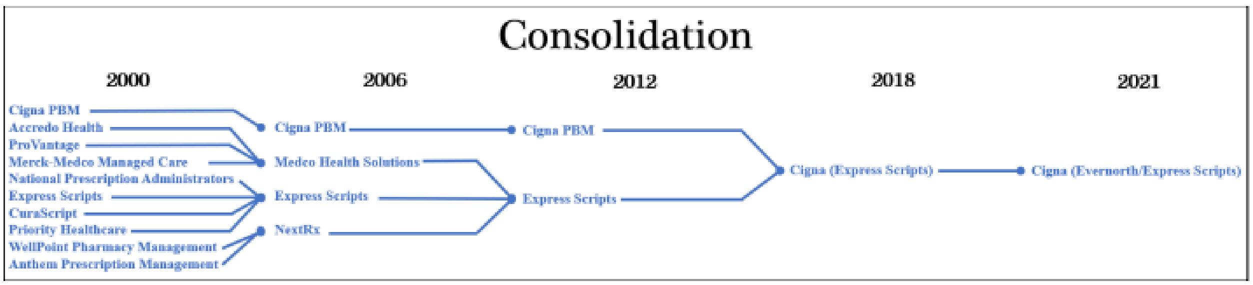
cc. In 2012, Express Scripts acquired Medco in a $29.1 billion deal.

dd. Prior to 2012, Express Scripts and Medco were separate companies. Standing alone, these companies were two of the largest PBMs in the country and had been since at least the mid-1990s.

ee. As a result of the merger, the combined Express Scripts was formed and became the largest PBM in the nation.

ff. Following the merger, all of Medco's PBM and data and research functions were combined into Express Scripts. The combined company (Medco and Express Scripts) continued under the name Express Scripts with all of Medco's clients becoming Express Scripts' clients and Medco's top executives becoming Express Scripts executives.

gg. The chart represents the consolidation of PBM entities that that are now all part of Express Scripts today:



hh. Express Scripts is now the largest PBM in the United States, with annual revenue (as of 2022) of over $100 billion. Express Scripts provides pharmacy benefit service to more than 100 million Americans, filling 1.4 billion prescriptions per year.

ii. At all times relevant hereto, Express Scripts offered pharmacy benefit management services nationwide and maintained standard, national formularies that were offered to and used by Express Scripts' clients nationwide, including in New York and Plaintiff's community. Express Scripts' national formularies include its National Preferred Formulary, Basic Formulary, High Performance Formulary, and Prime Formulary. These Express Scripts formularies were utilized by prescription drug benefit plans in Plaintiff's Community throughout the relevant time period.

At times relevant hereto, those formularies dictated the terms of reimbursement for opioids dispensed in New York and Plaintiff's Community.

jj. Express Scripts offers pharmacy benefit services to a variety of plan sponsors with covered lives in the Plaintiff's Community, including both large national companies and local/regional businesses.

kk. Express Scripts (and/or its predecessors) processed claims for opioids dispensed pursuant to Express Scripts' national formularies and standard UM guidelines in Plaintiff's Community throughout the opioid epidemic.

113. The OptuM Defendants

a. **Defendant UnitedHealth Group, Inc.** ("UnitedHealth Group" or "UHG") is a corporation organized under the laws of Delaware with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota, 55343.

b. UnitedHealth Group may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

c. UHG is registered to do business in New York and may be served through its registered agents: Griffin Michael, 914 3rd Avenue, Ste #126, Brooklyn, NY 11232 and Corporate Filings of New York, 90 State Street, Ste 700, Office 40, Albany, NY 12207.

d. UnitedHealth Group, Inc. is a Fortune 5 diversified managed healthcare company. In 2022, UnitedHealth Group listed revenue in excess of $324 billion. UnitedHealth Group, Inc. offers a spectrum of products and services including

health insurance plans and pharmacy benefits through its wholly-owned subsidiaries.

e. UnitedHealth Group operates through two connected divisions—Optum and UnitedHealthcare ("UHC"). As discussed in greater detail below, Optum provides PBM services; mail order pharmacy services; and data, analytics, consulting, and research services. UHC provides health insurance and health benefit services.

f. UnitedHealth Group, through its executives and employees, control the enterprise-wide policies that inform both UHC and Optum's lines of business in order to maximize profits across the corporate family.

g. UnitedHealth Group's conduct had a direct effect in New York, including Plaintiff's Community.

h. **Defendant Optum, Inc.** is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota.

i. Optum, Inc. is registered to do business in New York and may be served through its registered agent: CT Corporation System, 28 Liberty St., New York, NY 10005.

j. Optum, Inc. is a health services company managing the subsidiaries that administer UnitedHealth Group's pharmacy benefits, including OptumRx, Inc.

k. Since 2005, Optum, Inc. has been a part of the UnitedHealth Group. UnitedHealth Group has two major segments of its business: UnitedHealth Care ("UHC") which is its medical insurance arm and Defendant Optum, Inc., which includes UHG's PBM and research, data, and consulting arms. In 2022, UHC insured over 46 million Americans and generated $249 billion in revenue.

l. Optum, Inc. is engaged in five types of business activities: (1) data analytics; (2) pharmacy benefit management; (3) healthcare services; (4) mail-order pharmacy dispensing; and (5) medical discount card services.

m. **Defendant OptumInsight, Inc.** (f/k/a Ingenix, Inc.) is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. OptumInsight was formerly known as Ingenix, Inc. The name change came after the State of New York investigated Ingenix related to a scheme to defraud consumers by manipulating reimbursement rates, resulting in a $50 million settlement with the State and giving rise to U.S. Congressional hearings.

n. OptumInsight, Inc. is registered to do business in New York and may be served through its registered agent: CT Corporation System, 28 Liberty Street, New York, NY 10005.

o. OptumInsight, Inc. holds an active Third Party Administrator and Independent Adjuster license with the New York Department of Finance.

p. **Defendant OptumInsight Life Sciences, Inc.** (f/k/a QualityMetric, Inc.) is a Delaware corporation with its principal place of business located in Eden Prairie, Minnesota. OptumInsight Life Sciences, Inc. is a wholly-owned subsidiary of UnitedHealth Group ("UHG"). Prior to 2011, OptumInsight Life Sciences, Inc. was known as QualityMetric.

q. OptumInsight, Inc., OptumInsight Life Sciences, Inc., as well as their predecessors, successors, affiliates, including but not limited to Innovus, Innovus Research, i3, QualityMetric, HTAnalysts, ChinaGate, and CanReg, are referred to

herein as "OptumInsight." OptumInsight is the Optum group that engages in data analytics.

r. OptumInsight emerged from a collection of entities acquired by the UnitedHealth Group over the years. Those legacy entities include Innovus, QualityMetric, HTAnalysts, ChinaGate, CanReg, Ingenix, and the Lewin Group.

s. As discussed more fully below, OptumInsight partnered with various opioid manufacturers to create studies, marketing, educational programs, and even identifying algorithms to simultaneously downplaying opioids' addictive properties and expand its use and availability throughout the country, including in New York.

t. **Defendant OptumRx, Inc.** ("OptumRx") is a California corporation with its principal place of business at 2300 Main St., Irvine, California, 92614. OptumRx is the arm of Optum that provides PBM and pharmacy dispensing services.

u. OptumRx is registered to do business in New York and may be served through its registered agent: CT Corporation System, 28 Liberty St., New York, NY 10005.

v. OptumRx, Inc. entities (Optum Care Networks, Inc., Optum Services (Puerto Rico) LLC, OptumHealth Care Solutions Inc, OptumHealth Care Solutions LLC, and OptumInsight, Inc.) hold 4 active licenses with the New York State Department of Finance.

w. Prior to 2011, OptumRx was known as Prescription Solutions. In addition, as depicted in the PBM Consolidation Chart below, OptumRx grew as a result of numerous mergers and acquisitions. For example, in 2012, a large PBM, SXC Health Solutions, bought one of its largest rivals, Catalyst Health Solutions Inc. in a roughly $4.14 billion deal. Shortly thereafter, SXC Health Solutions Corp. renamed

the company Catamaran Corp. Following this, UHG bought Catamaran Corp. in a deal worth $12.8 billion and merged Catamaran with OptumRx.

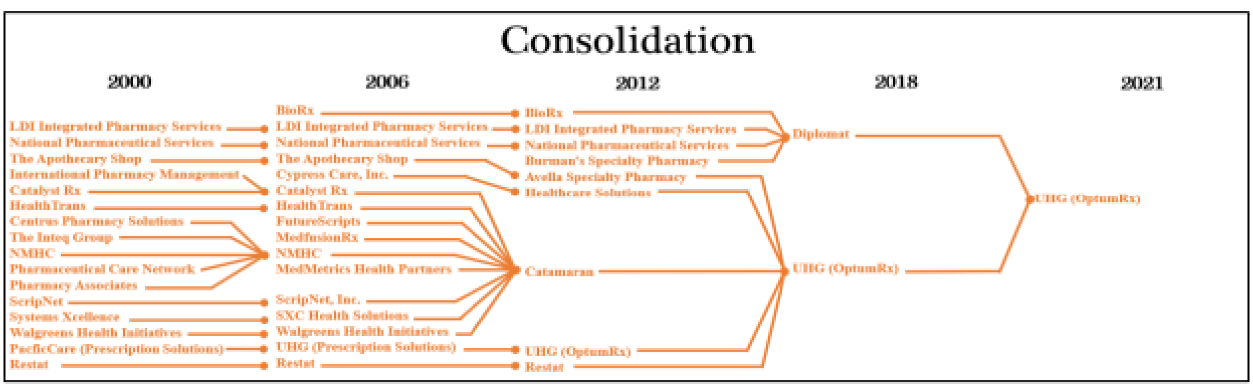
x. Prior to merging with OptumRx (or being renamed), Prescription Health Solutions, Catalyst Health Solutions, Inc., and Catamaran Corp. engaged in the at issue PBM and mail-order activities alleged more fully herein.

y. OptumRx now provides both PBM and mail-order dispensing services. At relevant times to this Complaint, OptumRx provided and/or offered PBM services for entities and/or persons in Plaintiff's Community.

z. At relevant times to this Complaint, OptumRx has sold and continues to sell prescription opioids through its mail order pharmacies in New York, including in Plaintiff's Community.

aa. OptumRx and all of its predecessors, including but not limited to Prescription Solutions, Catalyst Health Solutions, Inc., SXC Health Solutions Corp., and Catamaran Corp. are referred to herein as "OptumRx."

bb. The consolidations that led to the emergence of OptumRx in its current form are shown on the chart below:



cc. **Defendant OptumRx Discount Card Services, LLC** is a Delaware limited liability company with its principal place of business at 1423 Red Ventures Drive Building RV4, 3rd Floor, Fort Mill, South Carolina 29707.

dd. OptumRx Discount Card Services, LLC is registered to do business in New York and may be served through its registered agent: CT Corporation System, 28 Liberty St., New York, NY 10005 and at 111 eighth Avenue, New York, NY 10011.

ee. OptumRx Discount Card Services, LLC (f/k/a HealthTran, Inc., Catamaran PBM of Colorado, LLC, and Catamaran Discount Card Services, LLC) contracts with third-party businesses to administer prescription discount cards on their behalf. For example, the AARP's prescription discount card program is "endorsed" by the AARP, but is otherwise run by Optum Discount Card Services, which pays the AARP a royalty fee to the AARP for use of its intellectual property.

ff. Defendant Optum Perks, LLC is a Delaware limited liability company with its principal place of business in Livonia, Michigan.

gg. Optum Perks offers a free pharmacy discount card in New York.

hh. Optum Perks, LLC (f/k/a Script Relief, LLC) is a discount card program that originally started as a joint venture between Loeb Enterprises, LLC, and Catalyst, where by 2012 Catalyst had a 47% ownership interest. Per Catamaran's 2012 10-K, "Script Relief is a variable interest entity with Catamaran being the primary beneficiary, as the Company's underlying PBM and pharmacy contracts represent Script Relief's key business operations and the Company has the power to direct these activities."

ii. By 2019, OptumRx, Inc. had fully acquired Script Relief and renamed the program Optum Perks.

jj. **Defendant OptumHealth Care Solutions, LLC** is a Delaware limited liability company with its principal place of business at 11000 Optum Cir., Eden Prairie, Minnesota 55344.

kk. OptumHealth Care Solutions, LLC is registered to do business in New York and may be served through its registered agent: CT Corporation System, 28 Liberty St., New York, NY.

ll. Additionally, OptumHealth Care Solutions, LLC holds an active license with the New York State Department of Finance.

mm. OptumHealth for a number of years partnered with Purdue to educate many case managers, nurse practitioners, and medical directors throughout UnitedHealth Group's various enterprises. These programs were specifically endorsed and coordinated through one of Optum Health's national medical directors. The content of these programs targeted pain as an undertreated disease, among other issues, and contained the similar dangerous messaging regarding the use of OxyContin that Purdue plead guilty to in 2007.

nn. **Defendant OptumHealth Holdings, LLC** is a Delaware limited liability company with its principal place of business at 11000 Optum Cir., Eden Prairie, Minnesota 55344.

oo. **Defendant Optum Health Networks, Inc.** is a Delaware corporation with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota 55343.

pp. Optum Health Networks, Inc. is registered to do business in New York and may be served through its registered agent: CT Corporation System, 28 Liberty St., New York, NY.

qq. Optum Health Networks, Inc. provides care services to enrolled members of its subsidiaries and parents that includes care management services, arranging for delivery of services, and managing client relationships and contracts for access to said services.

rr. Together, OptumHealth Care Solutions, LLC, Optum Health Holdings, LLC, and OptumHealth Networks, Inc. are referred to herein as "OptumHealth."

ss. OptumHealth is a healthcare service provider that includes specialty health services, health banking services, ancillary care networks, and health education and information services to both individuals and health care professionals. It does this through four main lines of business: Care Solutions, Behavioral Solutions, Specialty Benefits, and Financial Services. In 2022, OptumHealth served 102 million individuals.

tt. Relevant to the opioid epidemic and Plaintiff's claims—detailed infra—OptumHealth partnered with Purdue throughout the 2000s to provide "education" to health care providers, including medical directors, nurse practitioners, case managers, and care advisors throughout the country regarding the so-called "undertreatment" of pain and expanding the use of opioids.

uu. Collectively, OptumRx, Optum, Inc., Optum Discount Card Services, LLC, Optum Perks, LLC, OptumHealth Care Services, LLC, OptumHealth Holdings, LLC,

Optum Health Networks, Inc., and OptumInsight are referred to herein as "Optum."

vv. Optum is named as a Defendant in its capacities as a: (1) PBM; (2) data, analytics, consulting, and research provider; and (3) mail-order pharmacy. During the relevant time period, Optum contracted directly with opioid manufacturers in each of these capacities. At times relevant to this Complaint, Optum performed these services and derived substantial revenue in New York, including in Plaintiff's Community.

ww. Optum, Inc. is a health services company comprising three sectors— OptumRx, which manages pharmacy benefits for both UHC and third party clients; OptumHealth, which provides medical services as well as education and support for individuals throughout the country; and OptumInsight, which is the data, research, and consulting sector.

xx. OptumRx is the third largest PBM in the United States. It provides PBM services to more than 65 million people.

yy. OptumRx offered pharmacy benefit management services nationwide and maintained standard, national formularies that were offered to and used OptumRx's clients both across the country and in Plaintiff's Community. At all times relevant hereto, those formularies included opioids, including those at issue in this case. OptumRx national formularies include the Essential Health Benefits, Generic Centric, Core Standard, Core Choice, Select Standard, Select Choice, Premium Standard, and Premium Choice.

zz. Optum (and/or its predecessors) processed claims for opioids dispensed pursuant to Optum's standard, national formularies and utilization management guidelines in Plaintiff's Community throughout the opioid epidemic.

aaa. In addition to its pharmacy benefit services, Optum entities also provide services related to pharmaceutical reimbursement and dispensing that generate revenue and benefit from a lack of opioid controls.

bbb. At times relevant hereto, Optum offered mail-order pharmacy services and dispensed opioids in New York, including Plaintiff's Community.

ccc. In 2021, Optum's mail order pharmacy was the fourth largest dispensing pharmacy in the United States and received $34.2 billion in prescription revenues.

ddd. From 2006 to 2014, Optum's mail order pharmacy bought over 4.5 billion MMEs of opioids spread over 252 million opioid dosage units.

eee. OptumInsight, Optum's data, research, and consulting arm, is one of the largest health information, technology, and consulting companies in the world. It collects, processes, sells and profits from the vast data all managed lives—which in 2011 covered over 75 million lives. It also provides clinical research, consulting, marketing advisory services, and analytics tools to its clients.

fff. OptumInsight is an integral part of the conduct that gives rise to Plaintiff's causes of action. As alleged in detail herein, throughout the relevant time period, OptumInsight worked directly with opioid manufacturers to convince patients, prescribers, payors and the public that long term opioid use was appropriate for the treatment of chronic pain and that opioids were not addictive.

ggg. Each opioid manufacturer had dedicated executives assigned to work with OptumInsight. The opioid manufacturers used their relationships with OptumInsight to deepen their ties to the overall Optum corporate family.

hhh. OptumInsight was paid tens of millions of dollars by the opioid manufacturers during the relevant time period for its work to expand the opioid market.

iii. Plaintiff adopts and incorporates into this complaint the allegations stated in paragraphs 203 through 506 in the document entitled "Plaintiff The City of Rochester, New York's Supplemental and Amended Allegations to be Added to the Verified Complaint and Jury Demand," Docket #5346-1, from case 1:17-md-02804-DAP.

F. Defendants' Agents

114. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

CONTINUING VIOLATIONS

115. This Complaint alleges a continuing course of conduct (including conduct within the limitations periods), and Defendants' unlawful conduct has inflicted continuing and accumulating harm within the applicable statutes of limitations. Thus, Plaintiff can recover for damages that it suffered during any applicable limitations period.

FACTUAL ALLEGATIONS

I. THE OPIOID EPIDEMIC

116. Since passage of the Controlled Substances Act ("CSA") in 1970, 21 U.S.C. § 801, et seq., opioids have been regulated as controlled substances. Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety.

117. Opioids generally have been categorized as Schedule II, although some are classified as Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 812. Schedule II drugs may not be dispensed without an original copy of a manually signed prescription, which may not be refilled, from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829.

118. Opioids provide effective treatment for short-term, post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Defendants, however, have manufactured, promoted, marketed, and distributed opioids for the management of chronic pain by misleading consumers and medical providers, such as Independent Emergency Room Physicians, through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

119. The past two decades have been characterized by increasing abuse and diversion of prescription drugs, including opioid medications, in the United States.[43]

120. Prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every four (4) hours for one (1) month.[44]

121. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, declared prescription painkiller overdoses at epidemic levels. The News Release noted:

> • The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
>
> • More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).
>
> • Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
>
> • The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.
>
> • Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.

---

[43] *See Richard C. Dart et al.*, Trends in Opioid Analgesic Abuse and Mortality in the United States, 372 N. Eng. J. Med. 241 (2015).
[44] Katherine M. Keyes *et al.*, Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States, 104 Am. J. Pub. Health e52 (2014).

- Almost 5,500 people start to misuse prescription painkillers every day.[45]

122. In a November 2016 report, the DEA declared opioid prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the United States.[46]

123. According to the CDC, opioids are responsible for the majority of drug overdoses today.[47] Additionally, opioid overdose have quadrupled nationally since 1999.[48]

124. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.[49]

125. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).

[45] *See* Press Release, Centers for Disease Control and Prevention, Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101 flu pain killer overdose.html.

[46] William Wan & Mark Berman, *States to Try New Ways of Executing Prisoners. Their Latest Idea? Opioids.*, THE WASHINGTON POST (Dec. 9, 2017), https://www.washingtonpost.com/national/health-science/states-choose-new-ways-to-execute-prisoners-their-latest-idea-opioids/2017/12/09/3eb9bafa-d539-11e7-95bf-df7c19270879 story.html?utm term=.c7048831bfcd.

[47] Centers for Disease Control and Prevention, *Heroin Overdose Data*, https://www.cdc.gov/drugoverdose/data/heroin.html (last accessed April 12, 2018).

[48] Id.

[49] *See* Nora D. Volkow, M.D. & A. Thomas McLellan, M.D., *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, 374 N Engl J Med 1253-1263 (2016), DOI: 10.1056/NEJMra1507771, http://www.nejm.org/doi/full/10.1056/NEJMra1507771, (hereinafter "Volkow and McLellan").

126. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.

127. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.

128. Almost 5,500 people start to misuse prescription painkillers every day.[50]

129. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year. [51]

130. Across the nation, emergency rooms are struggling with a wicked, ever-expanding epidemic of opioid addiction and abuse. Every day, more than 90 Americans lose their lives after overdosing on opioids. [52]

131. The National Institute on Drug Abuse identifies misuse and addiction to opioids as an epidemic. [53]

---

[50] See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html (accessed Jul. 12, 2018).

[51] See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Provisional Counts of Drug Overdose Deaths, (August 8, 2016), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf (accessed Jul. 12, 2018)

[52] Opioid Crisis, NIH, National Institute on Drug Abuse (available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-crisis,(accessed July. 12, 2018) ("Opioid Crisis, NIH") (citing at note I Rudd RA, Seth P, David F, Scholl L, Increases in Drug and Opioid Involved Overdose Deaths - United States, 2010-2015, MMWR MORE MORTAL WKLY REP. 2016;65, doi:10.15585/mmwr.mm655051el).

[53] *See* Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").

132. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the "grave risks" of opioids, including "addiction, overdose, and even death." The FDA further warned, "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death." Because of those grave risks, the FDA said that long-acting or extended release opioids "should be used only when alternative treatments are inadequate."[54] The FDA required that—going forward—opioid makers of long-acting formulations clearly communicate these risks on their labels.

133. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release for opioid pain medications as it had for extended release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.[55]

134. The facts on which the FDA relied in 2013 and 2016 were well known to Defendants for many years since they began marketing these drugs.

135. On March 29, 2017, then President Trump created The President's Commission on Combating Drug Addiction and the Opioid Crisis. On November 1, 2012 the Commission issued its final report and recommendations.

---

[54] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physician for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[55] FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm (accessed July 12, 2018).

136. The President's Commission on Combating Drug Addiction and the Opioid Crises found "Contributors to the Current Crisis" in the U. S. to include, among other things:

- Use of the Porter & Jick letter to make unsubstantiated claims by pharmaceutical companies;
- The lack of high quality evidenced demonstrating that opioid can be used safely for chronic non-terminal pain;
- The use of the phrase "pain as the fifth vital sign, by the APS, JCAHO and others; and
- The fact that "[t]o this day, the opioid pharmaceutical industry influences the nation's response to the crisis.

137. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or continuing to the national, state, and local opioid epidemic.

II. THE MANUFACTURER DEFENDANTS' FALSE, DECEPTIVE AND UNFAIR MARKETING OF OPIOIDS

138. The opioid epidemic did not happen by accident.

139. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

140. Each Manufacturer Defendant has conducted, and has continued to conduct, a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

141. The Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of "pseudo addiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

142. The Manufacturer Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, and through unbranded marketing and industry-funded front groups.

143. Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[56] In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors ... [m]any of [whom] were even taught - incorrectly - that opioids are not addictive when prescribed for legitimate pain.[57] This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often tum to the street to by prescription opioids or even non-prescription opioids, like heroin.

144. The Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

145. As alleged throughout this Complaint, Defendants' conduct created a public health crisis and a public nuisance.

146. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm can be abated by, *inter alia*, (a) educating prescribers and patients regarding the true risks and benefits of opioids,

[56] *See* Katherine Eban, Oxycontin: Purdue Pharma 's Painful Medicine, Fortune, Nov. 9, 2011. http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/ (accessed July 13, 2018); David Crow, Drugmakers Hooked on $l0bn Opioid Habit, Fin. Times, Aug. 10,2016, https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95 (accessed July 12, 2018).
[57] Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), http://time.com/4468400/surgeon-general-letter-opioid-addiction/ (accessed July 17, 2018).

including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment to patients who are already addicted to opioids; (c) increasing the use of medically assisted treatment (MAT) in the emergency room, (d) providing "warm handoff" abilities for emergency room physicians and (e) making naloxone widely available so that overdoses are less frequently fatal.

147. Defendants have the ability to act to abate the public nuisance, and the law recognizes that they are uniquely well positioned to do so. It is the manufacturer of a drug that has primary responsibility to assure the safety, efficacy, and appropriateness of a drug's labeling, marketing, and promotion. And, all companies in the supply chain of a controlled substance are primarily responsible for ensuring that such drugs are only distributed and dispensed to appropriate patients and not diverted. These responsibilities exist independent of any FDA or DEA regulation, to ensure that their products and practices meet both federal and state consumer protection laws and regulations. As registered manufacturers and distributors of controlled substances, Defendants are placed in a position of special trust and responsibility, and are uniquely positioned, based on their knowledge of prescribers and orders, to act as a first line of defense.

A. Each Manufacturer Defendant Used Multiple Avenues To Disseminate Their False And Deceptive Statements About Opioids

148. The Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients throughout the United States. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State and Plaintiff's community.

149. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that the Manufacturer Defendants' messages are accurately and consistently delivered across marketing channels - including detailing visits, speaker events, and advertising - and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

150. The Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. The Manufacturer Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

151. The Manufacturer Defendants' misrepresentations fall into the following nine categories:

a. The risk of addiction from chronic opioid therapy is low;

b. To the extent there is a risk of addiction, it can be easily identified and managed;

c. Signs of addictive behavior are "pseudoaddiction," requiring more opioids;

d. Opioid withdrawal can be avoided by tapering;

e. Opioid doses can be increased without limit or greater risks;

f. Long-term opioid use improves functioning;

g. Alternative forms of pain relief pose greater risks than opioids;

h. A version of Oxycontin marketed by Purdue was effective in providing 12 hour pain relief; and

i. New formulations of certain opioids successfully deter abuse.

152. Each of these propositions was false. The Manufacturer Defendants knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids. While each Manufacturer Defendant deceptively promoted their opioids specifically, and, together with other Manufacturer Defendants, opioids generally, not every Manufacturer Defendant propagated (or needed to propagate) each misrepresentation. Each Manufacturer Defendant's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risk and benefits of opioids.

153. Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs using one or more of the types of misrepresentations above. Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*. Defendants' advertising budgets peaked in 2011, when they collectively spent more than $14 million on the medical journal advertising of opioids, nearly triple what they spent in 2001. The 2011 total includes $4.9 million by Janssen.[58]

154. A number of these branded advertisements deceptively portrayed the benefits of opioid therapy for chronic pain including that the risk of addiction was low although there was no

[58] In 2011, Actavis spent less than $100,000 on such advertising, and Cephalon spent nothing. These companies' medical journal advertising peaked earlier, with Actavis spending $11.7 million in 2005, and Cephalon spending about $2 million in each of 2007 and 2008.

evidence to support those claims. In fact, studies have shown that a substantial percentage of long term users of opioids experience addiction and addiction can result from any use. [59]

155. The pattern of misrepresentation of the product and the addictive nature is illustrated by actions of Non-Defendant Purdue. Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this "research" in the form of a one-paragraph letter to the editor published in the New England Journal of Medicine ("NEJM") in 1980.[60]

156. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction "rare" for patients treated with opioids.[84] They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients' records.

157. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.[61]

---

[59] FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics, FDA (Sept. 10, 2013); *see also* FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death, FDA (Mar. 22, 2016).

[60] Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N Engl J Med. 123 (Jan. 10, 1980), http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

[61] *Pain Killer*, supra n. 34, at 174.

158. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper.[62] Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Marketing Defendants used it to assert that their opioids were not addictive, "that's not in any shape or form what we suggested in our letter," according to Dr. Jick.

159. A 2005 Purdue advertisement for OxyContin that ran in the *Journal of Pain* touted the drug as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a man and boy fishing and proclaimed that "There Can Be Life With Relief." This depiction falsely implied that OxyContin provides both effective long-term pain relief and functional improvement, claims that, as described below, are unsubstantiated and contradicted in medical literature.

160. Janssen misrepresented the addiction risk of opioids on its websites and print materials. One website, *Let's Talk Pain*, states, among other things, that "the stigma of drug addiction and abuse" associated with the use of opioids stemmed from a "lack of understanding addiction." (Although Janssen described the website internally as an unbranded third-party program, it carried Janssen's trademark and copy approved by Janssen.)

[62] J. Porter & H. Jick, Addiction Rare in Patients Treated with Narcotics, 302(2) New. Eng. J. Med. 123 (1980).

161. A Janssen unbranded website, *PrescribeResponsibly.com*, states that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."[63]

162. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which included claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." Similarly, Cephalon sponsored APF's *Treatment Options*: *A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

163. Through its "Learn More about customized pain control with Kadian," material, Actavis claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is "less likely" to happen in those who "have never had an addiction problem." The piece goes on to advise that a need for a "dose adjustment" is the result of tolerance, and "not addiction."

164. Each Marketing Defendant had similar promotional materials misrepresenting the addictive nature of opioids.

165. Each Manufacturer Defendant also promoted the use of opioids for chronic pain through "detailers" - sales representatives who visited individual doctors and medical staff in their offices - and small-group speaker programs. The Manufacturer Defendants have not corrected this misinformation. Instead, each Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, the Manufacturer Defendants spent in excess

---

[63] Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last modified July 2, 2015).

of $168 million on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

166. Defendants developed sophisticated plans to select prescribers for sales visits based on their specialties and prescribing habits. In accordance with common industry practice, Defendants purchase and closely analyze prescription sales data from IMS Health. This data allows them to precisely track the rates of initial prescribing and renewal by individual doctors, which in turn allows them to target, tailor, and monitor the impact of their appeals.

167. Defendants, in particular, relied upon "influence mapping," *i.e.*, using decile rankings or similar breakdowns to identify the high-volume prescribers on whom detailing would have the greatest sales impact. Defendants also closely monitored doctors' prescribing after a sales representative's visit to allow them to refine their planning and messaging and to evaluate and compensate their detailers.

168. Sales representatives marketed OxyContin as a product "to start with and to stay with."[64] Sales representatives also received training in overcoming doctors' concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. One of Purdue's early training memos compared doctor visits to "firing at a target," declaring that "[a]s you prepare to fire your 'message,' you need to know where to aim and what you want to hit!"[65]According to the memo, the target is physician resistance based on concern about addiction: "The physician wants pain relief for these patients without addicting them to an opioid."[66]

[64] Keefe, *Empire Of Pain*
[65] *Pain Killer,* supra n. 34, at 102.
[66] Id.

169. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors' objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that "it's just too addictive."[67] May and his coworkers were trained to "refocus" doctors on "legitimate" pain patients, and to represent that "legitimate" patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less "habit-forming" than painkillers that need to be taken every four hours.

170. In addition to making sales calls, Defendants' detailers also identified doctors to serve, for payment, on Defendants' speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. Defendants almost always selected physicians who were "product loyalists," as they were sure to be asked whether they prescribe the drug themselves.

171. Defendants devoted massive resources to these direct sales contacts with prescribers. In 2014, Defendants collectively spent $60 million on detailing branded opioids to physicians nationwide. This figure includes $34 million by Janssen, $13 million by Cephalon, and $2 million by Actavis. The total figure is more than double Defendants' collective spending on detailing in 2000. Detailers' role in Defendants' overall promotional efforts was also carefully calibrated.

172. **Indirect Marketing -** Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs. A drug company's branded marketing, which identifies and promotes a specific drug, must:

[67] David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), The New Yorker (Oct. 27, 2017), https://www.newyorker.com/podcast/the-new- yorker-radio-hour/how-oxycontin-was-sold-to-the-masses.

(a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.[68] The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients.

173. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits the sale in interstate commerce of drugs that are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular."[69] "Adequate directions for use" are directions "under which the layman can use a drug safely and for the purposes for which it is intended."[70] "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material.[71] "The term "accompanying" is interpreted broadly to include promotional materials—posters, websites, brochures, books, and the like—disseminated by or on behalf of the manufacturer of the drug.[72] Thus, Defendants' promotional materials are part of their drugs' labels and are required to be accurate, balanced, and not misleading.

174. Labeling is misleading if it is not based on substantial evidence, if it materially misrepresents the benefits of the drug, or if it omits material information about or minimizes the frequency or severity of a product's risks. "The most serious risks set forth in a product's labeling are generally material to any presentation of efficacy." The FDA notes that

---

[68] 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6).
[69] 21 U.S.C. §§ 352.
[70] 21 C.F.R. § 201.5.
[71] 21 U.S.C. § 321(m).
[72] See *id*.

"[b]ecause people expect to see risk information, there is no reason for them to imagine that the product has important risks that have been omitted . . . especially if some risks are included."[73] Promotion that fails to present the most important risks of the drug as prominently as its benefits lacks fair balance and is therefore deceptive.

175. It is also illegal for drug companies to distribute materials that exclude contrary evidence or information about the drug's safety or efficacy or present conclusions that "clearly cannot be supported by the results of the study."[74] Further, drug companies must not make comparisons between their drugs and other drugs that represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience."[75]

176. While the FDA must approve a drug's label, it is the drug company's responsibility to ensure that the material in its label is accurate and complete and is updated to reflect any new information.[76] Promotional materials also must be submitted to the FDA when they are first used or disseminated. The FDA does not have to approve these materials in advance; if, upon review, the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning

[73] FDA, Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion, May 2009, at 14.
[74] 21 C.F.R. § 99.101(a)(4).
[75] 21 C.F.R. § 202.1(e)(6)(ii).
[76] See 21 C.F.R. § 201.56 (providing general requirements for prescription drug labeling); see also *Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 C.F.R. § 314.70(c)(6) (iii)(A-C) (allowing manufacturers to make changes that "strengthen . . . a warning, precaution, or adverse reaction" or "strengthen a statement about drug abuse, dependence, psychological effect, or overdosage").

letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

177. The FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient. Senior FDA officials met with Purdue on April 23, 2001, to "provide comments and suggestions on a Risk Management program for OxyContin." Among other issues, the FDA noted that Purdue should add a black-box warning for overdose, abuse, and death to OxyContin's label. Purdue acknowledged that it was aware of abuse of OxyContin orally (without tampering), as well as by snorting or injecting. It was not, the FDA explained, a matter of changing a few words in OxyContin's label; Dr. Cynthia McCormick, then director of the FDA division overseeing pain medication, declared that "'major overhaul is my message.' The prescribing of OxyContin is creeping into a whole population of people where it doesn't belong. Just rewriting the abuse and dependence section won't help much, that part of the insert is not a pivot point."

178. Purdue narrowed the recommended use of OxyContin to situations when "a continuous, around-the-clock analgesic is needed for an extended period of time" and added a warning that "[t]aking broken, chewed, or crushed OxyContin tablets" could lead to a "potentially fatal dose." However, Purdue did not, until 2014, change the label as the FDA suggested, to indicate that OxyContin should not be the first therapy, or even the first opioid, used, and did not disclose the incidence or risk of overdose and death even when OxyContin was not abused. Purdue announced the label changes in a letter to health care providers but did not, as the FDA suggested, issue "a Medguide for patients on the risks of overdose and the abuse of opioids as well as risks for use by others than those for whom it was prescribed" or undertake the recommended promotional effort to educate patients about the potentially fatal risks of OxyContin.

179. The Manufacturer Defendants' indirectly marketed their opioids using unbranded advertising, paid speakers and "key opinion leaders" ("KOLs"), influenced guidelines and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups").

180. Even where such unbranded messages were channeled through third-party vehicles, Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete. Unbranded brochures and other materials that are "disseminated by or on behalf of [the] manufacturer" constitute drug "labeling" that may not be false or misleading in any particular. *See* 21 C.F.R. §202.1(e)(7)(l)(2).[77] Defendants' sales representatives distributed third-party marketing material that was deceptive to Defendants' target audiences. Defendants are responsible for these materials.

181. CMEs are ongoing professional education programs provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but to get information on new

[77] This regulation provides: "Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and the references published . . . containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling, as defined in section 201(m) of the act." As labeling, such third party-created content distributed by a drug company may not be misleading and must meet the accuracy, substantiation, and fair balance requirements in the FDCA.

developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs are typically delivered by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

182. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of focus and lack of specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to Defendants' deceptions.

183. In all, Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

184. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."[78]

---

[78] Opinion 9.0115, Financial Relationships with Industry in CME, Am. Med. Ass'n (Nov. 2011), available at

185. The influence of Defendants' funding on the content of these CMEs is clear. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death 26 times. Students who read the industry-funded article more frequently noted the impression that opioids were underused in treating chronic pain. The "take-aways" of those reading the non- industry-funded CME mentioned the risks of death and addiction much more frequently than the other group. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty health care providers have in screening and accounting for source bias.[79]

186. By sponsoring CME programs presented by Front Groups like APF, AAPM, and others, Defendants could expect messages to be favorable to them, as these organizations were otherwise dependent on Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and Defendants measured the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

---

https://www.ama-assn.org/delivering-care/financial-relationships-industry-continuing-medical-education (accessed July 13, 2018).

[79] Adriane Fugh-Berman, Marketing Messages in Industry-Funded CME, PharmedOut (June 25, 2010), available at www.pharmedout.org/pdf/Conf2010/Fugh-BermanPrescriptionforConflict6-25-10.pdf (accessed July 13, 2018).

187. For example, Purdue sponsored a 2011 CME taught by KOL Lynn Webster via webinar titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation also deceptively instructed prescribers that screening tools, patient agreements, and urine test prevented "overuse of prescriptions" and "overdose deaths." At the time, Dr. Webster was receiving significant funding from Purdue. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Purdue (and other Defendants). The webinar was available to and was intended to reach Charleston County prescribers.

188. Purdue also sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. *Path of the Patient* was devoted entirely to the message of treating chronic pain with opioids. Although the program purported to instruct a treating physician how to manage chronic pain in younger adults at risk for abuse, it does no such thing.

189. This "educational" program, addressing treatment of a population known to be particularly susceptible to opioid addiction, presents none of the alternative treatment options available, only discussing treatment of chronic pain with opioids.

190. In a role-play in *Path of the Patient*, a patient who suffers from back pain tells his doctor that he is taking twice as many hydrocodone pills as directed. The doctor reports that the pharmacy called him because of the patient's early refills. The patient has a history of drug and alcohol abuse. Despite these facts, the narrator notes that, because of a condition known as "pseudoaddiction," the doctor should not assume his patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor in the role- play treats this patient by prescribing a high-dose, long-acting opioid. This CME was available online and was intended to reach Charleston County prescribers.

191. Purdue also sponsored a CME titled *Overview of Management Options* issued by the American Medical Association in 2003, 2007, and 2013 (the latter of which is still available for CME credit). The CME was edited by KOL Russel Portenoy, among others. It deceptively instructs physicians that NSAIDs and other drugs, but not opioids, are unsafe at high doses. In reality, the data indicates that patients on high doses of opioids are more likely to experience adverse outcomes than patients on lower doses of the drugs. Dr. Portenoy received research support, consulting fees, and honoraria from Purdue (among others), and was a paid Purdue consultant. This CME was presented online in the United States and was available to prescribers.

192. The Manufacturer Defendants marketed through third-party, **unbranded advertising** to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long term opioid use for chronic pain.

193. Rather than find a way to actually test the safety and efficacy of opioids for long- term use, Defendants led people to believe that they already had. Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to shape the perceptions of prescribers, patients and payors. This literature was, in fact, marketing material

focused on persuading doctors and consumers that the benefits of long-term opioid use outweighed the risks.

194. To accomplish this, Defendants—sometimes through third-party consultants and/or advocacy organizations—commissioned, edited, and arranged for the placement of favorable articles in academic journals. Defendants' internal documents reveal plans to submit research papers and "studies" to long lists of journals, including back-up options and last resort, "fast-track" application journals, which they could use if the pending paper was rejected everywhere else.

195. Defendants coordinated the timing and publication of manuscripts, abstracts, posters/oral presentations, and educational materials in peer-reviewed journals and other publications to support the launch and sales of their drugs. The plans for these materials did not originate in the departments within the Defendant organizations that were responsible for research, development or any other area that would have specialized knowledge about the drugs and their effects on patients, but in Defendants' marketing departments and with Defendants' marketing and public relations consultants. Defendants often relied on "data on file" or presented posters, neither of which are subject to peer review. They also published their articles not through a competitive process, but in paid journal supplements, which allowed Defendants to publish, in nationally circulated journals, studies supportive of their drugs.

196. Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even where references distorted the significance or meaning of the underlying study. Most notably, Purdue promoted a 1980 reference in the well-respected *New England Journal of Medicine*: J. Porter & H. Jick, *Addiction Rare in Patients*

Treated with Narcotics, 302(2) *New Eng. J. Med.* 123 (1980) ("Porter-Jick Letter"). It is cited more than a thousand times in Google Scholar. It also appears as a reference in two CME programs in 2012 sponsored by Purdue and Endo.[80] Defendants and those acting on their behalf failed to reveal that this "article" is actually a letter-to-the-editor, not a peer-reviewed study (or any kind of study at all). The Porter-Jick Letter, reproduced in full below, describes a review of the charts of hospitalized patients who had received opioids. (Because it was a 1980 study, standards of care almost certainly would have limited opioids to acute or end-of-life situations, not chronic pain.)

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug Surveillance Program
Boston University Medical Center
Waltham, MA 02154

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

197. As stated above, Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.[81]

[80] AAPM, Safe Opioid Prescribing Course, February 25-26, 2012, sponsored by Purdue and Endo; "Chronic Pain Management and Opioid Use," October 11, 2012, sponsored by Purdue. CMEs are available for online credit.
[81] *Pain Killer*, supra n. 34, at 174

198. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper.[82] Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Manufacturing Defendants used it to assert that their opioids were not addictive, "that's not in any shape or form what we suggested in our letter," according to Dr. Jick.

199. Purdue specifically used the Porter and Jick letter in its 1998 promotional video "I got my life back," in which Dr. Alan Spanos says "In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%.*"[83] Purdue trained its sales representatives to tell prescribers that fewer than 1% of patients who took OxyContin became addicted. (In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen per cent.)[84]

200. Other Defendants relied on and disseminated the same distorted messaging. The enormous impact of Defendants' misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases "grossly misrepresented." In particular, the authors of this letter explained:

---

[82] J. Porter & H. Jick, Addiction Rare in Patients Treated with Narcotics, 302(2) New. Eng. J. Med. 123 (1980).

[83] Our Amazing World, *Purdue Pharma OxyContin Commercial*,

https://www.youtube.com/watch?v=Er78Dj5hyeI, (last accessed Jan. 31, 2018) (emphasis added).

[84] Keefe, *Empire of Pain*.

> [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy.[85]

201. "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."[86]The Porter-Jick Letter notes that, when these patients' records were reviewed, it found almost no references to signs of addiction, though there is no indication that caregivers were instructed to assess or document signs of addiction. None of these serious limitations is disclosed when Defendants, or those acting on their behalf, cite the Porter-Jick Letter, typically as the sole scientific support for the proposition that opioids are rarely addictive, even when taken long-term when in fact, Dr. Jick later stated that was not the intent of his letter.

202. By way of another example, until at least February 2009, Non-Defendant Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as a noncommercial resource for healthcare professionals, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices.

203. Among other content, the website included a handout titled "Oxycodone Safety Handout for Patients," which advised practitioners that: "Patients' fears of opioid

[85] Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article.

[86] *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT (May 31, 2017), https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/

addiction should be dispelled."[87] The handout included several false and misleading statements concerning the risk of addiction associated with prescription opioids:

> Will you become dependent on or addicted to oxycodone?
>
> - After a while, oxycodone causes physical dependence. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
> - This is not the same as addiction, a disease involving a craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.[88]

204. Additionally, upon information and belief, the FAQ section of Pain-Topics.org contained false and misleading information downplaying the dangers of prescription opioid use including support for the term "pseudoaddiction."

205. Another document believed to be formerly available on the website, "Commonsense Oxycodone Prescribing & Safety," falsely suggests that generic oxycodone is less prone to abuse and diversion than branded oxycodone: "Anecdotally, it has been observed that generic versions of popularly abused opioids usually are less appealing; persons buying drugs for illicit purposes prefer brand names because they are more recognizable and the generics have a lower value 'on the street,' which also makes them less alluring for drug dealers."[89]

---

[87] Lee A. Kral & Stewart B. Leavitt, Oxycodone Safety Handout for Patients, Pain-Topics.Org (June 2007), http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf

[88] *Id*.

[89] Lee A. Kral, Commonsense Oxycodone Prescribing & Safety, Pain-Topics.org (June 2007), https://pdfs.semanticscholar.org/6bb9/f09b4bf2c9cc7b4eb9917985b301a6b0edce.pdf.

206. A brochure available on *Painknowledge.com* titled "*Pain: Opioid Facts*," an Endo-sponsored NIPC, stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted." Various defendants incorporated this language in brochures.

207. Defendants worked not only to create or elevate favorable studies in the literature, but to discredit or bury negative information. Defendants' studies and articles often targeted articles that contradicted Defendants' claims or raised concerns about chronic opioid therapy. In order to do so, Defendants—often with the help of third-party consultants—targeted a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

208. Defendants' strategies—first, to plant and promote supportive literature and then, to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicts those claims—are in dereliction of their legal obligations. The strategies were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits and superiority of opioids for chronic pain relief resulting in distorted prescribing patterns.

209. Defendants cultivated a small circle of doctors who, upon information and belief, were selected and sponsored by Defendants solely because they favored the aggressive treatment of chronic pain with opioids. Defendants' support helped these doctors become respected industry experts. In return, these doctors repaid Defendants by touting the benefits of opioids to treat chronic pain.

210. Pro-opioid doctors have been at the hub of Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of

opioid therapy for chronic pain. **KOLs** have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. They have served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain (even while acknowledging the lack of evidence in support of that position) and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to exert control of each of these modalities through their KOLs.

211. In return, the KOLs' association with Defendants provided not only money, but prestige, recognition, research funding, and avenues to publish. This positioned them to exert even more influence in the medical community.

212. Although some KOLs initially may have advocated for more permissive opioid prescribing with honest intentions, Defendants cultivated and promoted only those KOLs who could be relied on to help broaden the chronic opioid therapy market. Defendants selected, funded, and elevated those doctors whose public positions were unequivocal and supportive of using opioids to treat chronic pain.[90] These doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the drug companies.

213. Defendants cited and promoted favorable studies or articles by these KOLs. By contrast, Defendants did not support, acknowledge, or disseminate the publications of doctors

[90] Opioid-makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used KOLs in its effort to persuade the public and regulators that tobacco was not addictive or dangerous. For example, the tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low-tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.

critical of the use of chronic opioid therapy. Indeed, one prominent KOL sponsored by Defendants, Russell Portenoy, stated that he was told by a drug company that research critical of opioids (and the doctors who published that research) would never obtain funding. Some KOLs have even gone on to become direct employees and executives of Defendants, like Dr. David Haddox, Non-Defendant Purdue's Vice President of Risk Management.

214. Defendants provided substantial opportunities for KOLs to participate in research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature. As described by Dr. Portenoy, drug companies would approach him with a study that was well underway and ask if he would serve as the study's author. Dr. Portenoy regularly agreed.

215. Defendants also paid KOLs to serve as consultants or on their advisory boards and give talks or present CMEs, typically over meals or at conferences. Since 2000, Cephalon, for instance, has paid doctors more than $4.5 million for programs relating to its opioids.

216. These KOLs were carefully vetted to ensure that they were likely to remain on-message and supportive of a pharmaceutical industry agenda. One measure was a doctor's prior work for trusted Front Groups.

217. Defendants kept close tabs on the content of the misleading materials published by these KOLs. In many instances, they also scripted what these KOLs said—as they did with all their recruited speakers. The KOLs knew, or deliberately ignored, the misleading way in which they portrayed the use of opioids to treat chronic pain to patients and prescribers, but they continued to publish those misstatements to benefit themselves and Defendants, all the while causing harm to County prescribers and patients.

218. **Treatment guidelines** have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are otherwise not experts, nor trained, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Actavis and Non-Defendant Purdue discussed treatment guidelines with doctors during individual sales visits.

219. The **Federation of State Medical Boards ("FSMB")** is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

220. In 1998, the FSMB developed *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which FSMB admitted was produced "in collaboration with pharmaceutical companies."[91] The FSMB Guidelines taught not that opioids could be appropriate in limited cases or after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option. The FSMB Guidelines failed to mention risks relating to respiratory depression and overdose, and they discussed addiction only in the sense that "inadequate understandings" of addiction can lead to "inadequate pain control."

[91] FSMB, "Position of the FSMB in Support of Adoption of Pain Management Guidelines" (2000), http://www.painpolicy.wisc.edu/sites/default/files/sites/www.painpolicy.wisc.edu/files/FSMPwp.pdf

221. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from the 2004 guidelines, *Responsible Opioid Prescribing*, also make these same claims. These guidelines were posted online and were available to and intended to reach County physicians.

222. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Cephalon, nondefendant Endo, and Purdue. The FSMB financed the distribution of *Responsible Opioid Prescribing* by its member boards by contracting with drug companies, including Cephalon, for bulk sales and distribution to sales representatives (for distribution to prescribing doctors).

223. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed to state medical boards (and through the boards, to practicing doctors), and the FSMB benefitted by earning approximately $250,000 in revenue and commissions from their sale. The FSMB website describes the book as the "leading continuing medication education (CME) activity for prescribers of opioid medications."

224. Drug companies relied on FSMB guidelines to convey the message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head—doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught that they would be punished instead if they failed to prescribe opioids to their patients with pain.

225. FSMB, more recently, has moderated its stance. Although the 2012 revision of *Responsible Opioid Prescribing* continued to teach that "pseudoaddiction" is real and that opioid addiction risk can be managed through risk screening, it no longer recommended chronic opioid

therapy as a first choice after the failure of over-the-counter medication and has heightened its addiction and risk warnings.

226. **AAPM and the APS** are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013 (with AAPM receiving over $2 million).

227. They issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[92] The co-author of the statement, Dr. Haddox, was, at the time, a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement, which also formed the foundation of the FSMB Guidelines, remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.[93]

228. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines" or "Consensus Recommendation") and continued to recommend the use of opioids to treat chronic pain.[94] Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, and Purdue.

229. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is

[92] Consensus statement, The Use of Opioids for the Treatment of Chronic Pain, APS & AAPM (1997), available at https://www.jpain.org/article/S1082-3174(97)80022-0/pdf

[93] Id.

[94] Roger Chou et al., Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain, 10(2) The Journal of Pain: Official Journal of the American Pain Society 113-130 (2009)

manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Palm Beach County during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

230. Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

231. **The American Geriatrics Society ("AGS"),** a nonprofit organization serving health care professionals who work with the elderly, disseminated guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*, hereinafter "2009 AGS Guidelines"). The 2009 AGS Guidelines included the following recommendations: "All patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)," and "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[95] These recommendations, which continue to appear on AGS's website, are not

[95] Pharmacological Management of Persistent Pain in Older Persons, 57 J. Am. Geriatrics Soc'y 1331,1339, 1342 (2009), available at

supported by any study or other reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

232. AGS contracted with Janssen to disseminate the 2009 Guidelines, and to sponsor CMEs based on them. This defendant was aware of the content of the 2009 Guidelines when they agreed to provide funding for these projects. The 2009 Guidelines were first published online on July 2, 2009. AGS submitted grant requests to Defendants beginning July 15, 2009. Internal AGS discussions in August 2009 revealed that it did not want to receive up-front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate the publication. However, by drafting the guidelines knowing that pharmaceutical company funding would be needed, and allowing these companies to determine whether to provide support only after they had approved the message, AGS ceded significant control to these companies. Non-Defendant Endo, Janssen, and Purdue all agreed to provide support to distribute the guidelines.

233. According to one news report, AGS has received $344,000 in funding from opioid makers since 2009.[96] Five of 10 of the experts on the guidelines panel disclosed financial ties to Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Defendants, receiving grants from Defendants, and investing in Defendants' stock. The Institute of Medicine recommends that, to ensure an unbiased result, fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1532-5415.2009.02376.x (accessed July 13, 2018).

[96] John Fauber & Ellen Gabler, Narcotic Painkiller Use Booming Among Elderly, Milwaukee J. Sentinel, May 30, 2012.

234. The extent of **Defendants' influence on treatment guidelines** is demonstrated by the fact that independent guidelines—the authors of which did not accept drug company funding—reached very different conclusions. The 2012 *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that "[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence monitoring, in well- selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."[97]

235. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate

---

[97] Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment, 15 Pain Physician (Special Issue) S1-S66; Part 2—Guidance, 15 Pain Physician (Special Issue) S67-S116 (2012).

evidence that harms and costs exceed benefits based on limited evidence," while conceding there may be patients for whom opioid therapy is appropriate.[98]

236. The *Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued by the U.S. Department of Veterans Affairs ("VA") and Department of Defense ("DOD") in 2010, notes that their review:

> revealed the lack of solid evidence based research on the efficacy of long-term opioid therapy. Almost all of the randomized trials of opioids for chronic non-cancer pain were short-term efficacy studies. Critical research gaps . . . include: lack of effectiveness studies on long-term benefits and harms of opioids . . .; insufficient evidence to draw strong conclusions about optimal approaches to risk stratification . . .; lack of evidence on the utility of informed consent and opioid management plans . . .; and treatment of patients with chronic non-cancer pain at higher risk for drug abuse or misuse.[99]

237. As noted above, Defendants Cephalon, Janssen, and Purdue entered into arrangements with numerous organizations **or "Front Groups"** to promote opioids. These organizations depend upon Defendants for significant funding and, in some cases, for their survival. They were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting Defendants' marketing in other ways—for example, responding to negative articles and advocating against regulatory changes that

[98] American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids, (2011), available at: https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf (accessed July 13, 2018).

[99] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010), available at https://www.va.gov/painmanagement/docs/cpg_opioidtherapy_summary.pdf (accessed July 13, 2018).

would constrain opioid prescribing. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of opioids to treat chronic pain. Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages.

238. Several representative examples of such **Front Groups** are highlighted below, but there are others, too, such as APS, AGS, FSMB, American Chronic Pain Association ("ACPA"), AAPM, American Society of Pain Educators ("ASPE"), NPF, and PPSG.

239. The most prominent of Defendants' Front Groups was APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Purdue informed APF that the grant money reflected Purdue's effort to "strategically align its investments in nonprofit organizations that share [its] business interests," making clear that Purdue's funding depended upon APF continuing to support Purdue's business interests. Indeed, Purdue personnel participated in a March 2011 call with APF's "Corporate Roundtable," where they suggested that APF "[s]end ambassadors to talk about pain within companies and hospitals." Thus, Purdue suggested what role APF could play that would complement its own marketing efforts. On that call, Purdue personnel also committed to provide APF with a list of "industry state advocates" who could help promote chronic opioid therapy, individuals and groups that, upon information and belief, APF reached out to. Purdue personnel remained in constant contact with their counterparts at APF.

240. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into

a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason. This agreement demonstrates APF's lack of independence and its willingness to surrender to Purdue's control and commercial interests, which would have carried across all of APF's work.

241. Purdue used this agreement to conduct work with APF on the *Partners Against Pain* website. *Partners Against Pain* is a Purdue-branded site, and Purdue holds the copyright.

242. However, its ability to deploy APF on this project illustrates the degree of control Purdue exercised over APF. In 2011, it hired an APF employee to consult on the *Partners Against Pain* rollout, to orchestrate the media campaign associated with the launch of certain content on the website, and to make public appearances promoting the website along with a celebrity spokesperson. Purdue contemplated paying this consultant $7,500 in fees and expenses for 26 hours of work. Purdue would require this consultant to "to discuss and rehearse the delivery of [Purdue's] campaign messages" and Purdue committed that "[m]essage points will be provided to [the] Consultant in advance and discussed on [a planned] call." At all times, decisions regarding the final content on the *Partners Against Pain* website were "at the sole discretion of Purdue."

243. APF also volunteered to supply one of its staff (a medical doctor or a nurse practitioner) to assist Purdue as a consultant and spokesperson for the launch of one of Purdue's

opioid-related projects, *Understanding & Coping with Lower Back Pain*, which appeared on *Partners Against Pain*. One of the consultants was APF's paid employee, Mickie Brown. The consultant's services would be provided in return for a $10,000 consulting fee for APF and $1,500 in honoraria for the spokesperson. All documents used by the consultant in her media appearances would be reviewed and approved by individuals working for Purdue. It was not until later that APF worried about "how Purdue sees this program fitting in with our [existing] grant request."

244. Given the financial and reputational incentives associated with assisting Purdue in this project and the direct contractual relationship and editorial oversight, APF personnel were acting under Purdue's control at all relevant times with respect to *Partners Against Pain*.

245. APF acquiesced to Purdue's frequent requests that APF provide "patient representatives" for *Partners against Pain*. Moreover, APF staff and board members and Front Groups ACPA and AAPM, among others (such as Dr. Webster), appear on *Inthefaceofpain.com* as "Voices of Hope"—"champions passionate about making a difference in the lives of people who live with pain" and providing "inspiration and encouragement" to pain patients. APF also contracted with Purdue for a project on back pain in which, among other things, it provided a patient representative who agreed to attend a Purdue-run "media training session."

246. According to an Assurance of Voluntary Compliance ("AVC") entered into between the New York Attorney General and Purdue Pharma on August 19, 2015, *Inthefaceofpain.com* received 251,648 page views between March 2014 and March 2015. With the exception of one document linked to the website, *Inthefaceofpain.com* makes no mention of opioid abuse or addiction. Purdue's copyright appears at the bottom of each page of the website, indicating its ownership and control of its content. There is no other indication that 11 of the

individuals who provided testimonials on *Inthefaceofpain.com* received payments, according to the AVC, of $231,000 for their participation in speakers' programs, advisory meetings and travel costs between 2008 and 2013. The New York Attorney General found Purdue's failure to disclose its financial connections with these individuals had the potential to mislead consumers.

247. Nowhere was Purdue's influence over APF so pronounced as it was with the APF's "Pain Care Forum" ("PCF"). PCF was and continues to be run not by APF, but by Purdue's in-house lobbyist, Burt Rosen. As described by a former drug company employee, Rosen exercised full control of PCF, telling them "what to do and how to do it." This control allowed him, in turn, to run APF as, in accordance with Rosen's thinking, "PCF was APF, which was Purdue." PCF meets regularly in-person and via teleconference, and shares information through an email listserv.

248. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes—including death—among returning soldiers. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach County residents.

249. In addition to Perry Fine, Russell Portenoy, and Scott Fishman, who served on APF's Board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

250. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its

budget for 2010 projected receipts of roughly $2.9 million from drug companies out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from non-defendants Purdue, Cephalon, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

251. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. As laid out below, APF functioned largely as an advocate for the interests of Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

252. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications APF could pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

253. APF assisted in other marketing projects for drug companies. One project funded by another drug company—*APF Reporter's Guide: Covering Pain and Its Management* (2008)[100]—recycled text that was originally created as part of the company's training document.

[100] https://assets.documentcloud.org/documents/277606/apf-reporters-guide.pdf (accessed July 12, 2018)

254. The same drug company made general grants, but even then, it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, the company representative responded, "I provided an advocacy grant to APF this year—this would be a very good issue on which to use some of that. How does that work?"

255. The close relationship between APF and the drug company was not unique, but in fact mirrors the relationships between APF and Defendants. APF's clear lack of independence—in its finances, management, and mission—and its willingness to allow Defendants to control its activities and messages, support an inference that each Defendant that worked with APF was able to exercise editorial control over its publications.

256. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party and Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization and ceased to exist, effective immediately. In 2007, Purdue sponsored FSMB's *Responsible Opioid Prescribing*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Responsible Opioid Prescribing* also was drafted by Dr. Scott Fishman.

257. Purdue spent $150,000 to help FSMB distribute *Responsible Opioid Prescribing*. The book was distributed nationally

258. NIPC website, *Painknowledge.com*, claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living,

such as work and hobbies, that you were not able to enjoy when your pain was worse." In addition to "improved function," the website touted improved quality of life as a benefit of opioid therapy.

259. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

260. AAPM has received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintains a corporate relations council, whose members pay $25,000 per year (on top of other funding) to participate. The benefits include allowing members to present educational programs at off- site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors.

261. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

262. AAPM's staff understood that they and their industry funders were engaged in a common practice. Defendants were able to influence AAPM through both their significant and regular funding, and the leadership of pro-opioid KOLs within the organization.

B. *Manufacturer Defendants Embarked Upon A Campaign Of False, Deceptive And Unfair Assurances Grossly Overstating The Benefits Of The Opioid Drugs*

263. Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively present the risks, benefits, and superiority of opioids to treat chronic pain.

264. Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the same deceptive messages. These KOLs have worked reciprocally with Defendants to promote misleading messaging regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated to Palm Beach County prescribers and patients.

265. One vehicle for their collective collaboration was Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and to "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the Forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

266. PCF is comprised of representatives from opioid manufacturers and distributors (including Cephalon, Janssen, and Purdue); doctors and nurses in the field of pain care; professional organizations (*e.g.*, American Academy of Pain Management, APS, and American Society of Pain Educators); patient advocacy groups (*e.g.*, APF and ACPA); and other like-minded organizations (*e.g.*, FSMB and Wisconsin Pain & Policy Studies Group), almost all of which received substantial funding from Defendants.

267. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.[101] This was critical as a REMS that went too far in narrowing the uses or benefits, or highlighting the risks of chronic opioid therapy, would deflate Defendants' marketing efforts. The recommendations—drafted by Will Rowe of APF—claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers."[102] Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, and not undermine, their deceptive marketing of opioids for chronic pain.

267. Some illustrative examples of the Manufacturer Defendants' false claims are:

a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Non-defendant Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding

[101] The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

[102] Defendants also agreed that short-acting opioids should also be included in REMS as not to disadvantage the long-acting, branded drugs.

tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. Janssen sponsored and edited a patient education guide entitled Finding Relief Pain Management for Older Adults (2009) - which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

d. Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors' offices, of presumed patients in active professions; the caption read, "Pain doesn't fit into their schedules."

e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

f. Responsible Opioid Prescribing (2007), sponsored and distributed by Cephalon, Non-Defendant Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.

g. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give

[pain patients] a quality of life we deserve."[103] This publication is still available online.

h. Non-Defendant Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

i. Non-Defendant Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient." Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

j. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the "Let's Talk Pain" campaign, featured

[103] Am. Pam Found., Treatment Options: A Guide for People Living in Pain (2007) [hereinafter APF, Treatment Options], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

k. Purdue sponsored the development and distribution of APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain."[104]The Policymaker's Guide was originally published in 2011.[105]

l. Purdue's, Cephalon's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

268. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

269. There are eight primary misleading and unfounded representations. Defendants and the third parties with which they teamed:

a. misrepresented that opioids improve function;

b. misrepresented that opioids are safe and effective for long-term use;

c. concealed the link between long-term use of opioids and addiction;

d. misrepresented that addiction risk can be managed;

e. masked the signs of addiction by calling them “pseudo-addiction”;

f. falsely claimed withdrawal is easily managed;

---

[104] Am. Pain Found., A Policymaker's Guide to Understanding Pain and Its Management 6 (2011) [hereinafter APF, Policymaker's Guide], http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last accessed Jul. 12, 2018)

[105] *Id.*

g. misrepresented or omitted the greater dangers from higher doses of opioids; and deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs.

270. In addition to these misstatements, Purdue purveyed an eighth deception that OxyContin provides a full 12 hours of pain relief.

271. Exacerbating each of these misrepresentations and deceptions was the collective effort of Defendants and third parties to hide from the medical community the fact that the FDA "is not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[106]

272. Each of the following materials was created with the expectation that, by instructing patients and prescribers that opioids would **improve patients' function** and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to continue opioid therapy in the belief that failure to improve pain, function, or quality of life, could be overcome by increasing doses or prescribing supplemental short-acting opioids to take on an as-needed basis for breakthrough pain.

273. However, not only is there no evidence of improvement in long-term functioning, a 2006 study-of-studies found that "[f]or functional outcomes . . . other analgesics were significantly more effective than were opioids."[107] Studies of the use of opioids in chronic

[106] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[107] Andrea D. Furlan et al., Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects, 174(11) Can. Med. Ass'n J. 1589-1594 (2006). This study revealed that efficacy studies do not typically include data on opioid addiction, such that, if anything, the data overstate effectiveness.

conditions for which they are commonly prescribed, such as low back pain, corroborate this conclusion and have failed to demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity.[108] Indeed, one Defendant's own internal marketing plans characterized functional improvement claims as "aspirational." Another acknowledged in 2012 that "[s]ignificant investment in clinical data [was] needed" to establish opioids' effect on mitigating quality of life issues, like social isolation.

274. The long-term use of opioids carries a host of serious side effects, including addiction, mental clouding and confusion, sleepiness, hyperalgesia, and immune-system and hormonal dysfunction that degrade, rather than improve, patients' ability to function. Defendants often omitted these adverse effects as well as certain risks of drug interactions from their publications.

275. Yet each of the following statements by Defendants, suggests that the long-term use of opioids improve patients' function and quality of life, and that scientific evidence supports this claim.

276. **Actavis**

a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct prescribers that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy." (Emphasis added.)

[108] Moreover, users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users. They also were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

b. Documents from a 2010 sales training indicate that Actavis trained its sales force that increasing and restoring function is an expected outcome of chronic Kadian therapy, including physical, social, vocational, and recreational function.

c. Actavis distributed a product advertisement that claimed that use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and cause patients to enjoy their lives. The FDA warned Actavis that such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[109]

d. Actavis sales representatives told Charleston County prescribers that prescribing Actavis's opioids would improve their patients' ability to function and improve their quality of life.

277. **Cephalon**

[109] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at (https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf)

a. Cephalon sponsored the FSMB's Responsible Opioid Prescribing (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed the book through its pain sales force to 10,000 prescribers and 5,000 pharmacists.

b. Cephalon sponsored the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids, when used properly "give [pain patients] a quality of life we deserve." [110] The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs have greater risks associated with prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report. The publication is also currently available online.

c. Cephalon sponsored a CME written by key opinion leader Dr. Lynn Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape,

[110] Am. Pam Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, Treatment Options], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

LLC from September 28, 2007, to December 15, 2008. The CME taught that Cephalon's Actiq and Fentora improve patients' quality of life and allow for more activities when taken in conjunction with long- acting opioids.

d. Cephalon sales representatives told Charleston County prescribers that opioids would increase patients' ability to function and improve their quality of life.

277. Janssen

a. Janssen sponsored, developed, and approved content of a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and ASPMN, whose participation in *Let's Talk Pain* Janssen financed and orchestrated. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," inaccurately implying her experience would be representative.

b. Janssen provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "*increase* your level of functioning" (emphasis in the original). *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.

c. Janssen sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work.

278. **Purdue**

a. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals titled "Pain vignettes," which were case studies featuring patients, each with pain conditions persisting over several months, recommending OxyContin for each. One such patient, "Paul," is described as a "54-year- old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work more effectively.

b. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that "multiple clinical studies" had shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." [111] The sole reference for the functional improvement claim noted the absence of long-term studies and actually stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids." The *Policymaker's Guide* is still available online.

[111] APF, Policymaker's Guide, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (accessed July. 12, 2018)

c. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids, when used properly, "give [pain patients] a quality of life we deserve." APF distributed 17,200 copies in one year alone, according to its 2007 annual report. The guide is currently available online.[112]

d. Purdue sponsored APF's *Exit Wounds* (2009), which taught veterans that opioid medications "increase your level of functioning." *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.

e. Purdue sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Purdue also spent over $100,000 to support distribution of the book.

f. In 2012, Purdue disseminated a mailer to doctors titled "Pain vignettes." These "vignettes" consisted of case studies describing patients with pain conditions that persisted over a span of several

[112] Am. Pam Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, Treatment Options], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

months. One such patient, "Paul," is described as a "54-year-old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work. None of these ads, however, disclosed the truth—that there is no evidence that opioids improve patients' lives and ability to function and that there was substantial evidence to the contrary.

g. Purdue sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life.

278. **Long Term Use of Opioids** -There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. The first random, placebo- controlled studies appeared in the 1990s, and revealed evidence only for short-term efficacy and only in a minority of patients.

279. A 2004 report reviewed 213 randomized, controlled trials of treatments for cancer pain and showed that, while opioids had short-term efficacy, the data was insufficient to establish long-term effectiveness. Subsequent reviews of the use of opioids for cancer and non-cancer pain consistently note the lack of data to assess long-term outcomes. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long-term use. Similarly, a 2011 systematic review of studies for non-cancer pain found that evidence of long-term efficacy is poor. One year later, a similar review reported poor evidence of long-term efficacy for morphine, tramadol, and oxycodone, and fair evidence for transdermal fentanyl (approved only for use for cancer pain).

280. On the contrary, evidence exists to show that opioid drugs are not effective to treat chronic pain, and may worsen patients' health. A 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. Most notably, it stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids." Another review of evidence relating to the use of opioids for chronic pain found that up to 22.9% of patients in opioid trials dropped out before the study began because of the intolerable effects of opioids, and that the evidence of pain relief over time was weak.

281. Non-Defendant Endo's research shows that patients taking opioids, as opposed to other prescription pain medicines, report higher rates of obesity (30% to 39%); insomnia (9% to 22%); and self-described fair or poor health (24% to 34%).

282. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

283. As a pain specialist noted in an article titled Are We Making Pain Patients Worse?, "[O]pioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."

284. This is true both generally and for specific pain-related conditions. Studies of the use of opioids long-term for chronic lower back pain have been unable to demonstrate an improvement in patients' function. Conversely, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not help patients return to work or to physical activity. This is due partly to addiction and other side effects.

285. As many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches. Users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

286. The lack of evidence for the efficacy of opioid use long-term has been well-documented nationally in the context of workers' compensation claims, where some of the most detailed data exists. Claims involving workers who take opioids are almost four times as likely to reach costs of over $100,000 than claims without opioids, as these patients suffer greater side effects and are slower to return to work. Even adjusting for injury severity and self-reported pain score, taking an opioid for more than seven days and receiving more than one opioid prescription increased the risk that the patient would be on work disability one year later. A prescription for opioids, as the first treatment for a workplace injury, doubled the average length of the claim.

287. **Low Risk of Addiction -** Central to the Marketing Defendants' promotional scheme was the misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Marketing Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by "legitimate" pain patients. That, in turn, directly led to the expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Marketing Defendants and substantially contributing to the opioid epidemic.

288. Each of the Marketing Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to

support those claims. None of them have acknowledged, retracted, or corrected their false statements.

289. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, “even at recommended dose,”[113] and the risk substantially increases with more than three months of use.[114]As the CDC Guideline states, “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” (a diagnostic term for addiction).[115]

290. Some illustrative examples of the Manufacturer Defendants' false, deceptive, and unfair claims about the purportedly low risk of addiction include:

a. Actavis's predecessor caused a patient education brochure, Managing Chronic Back Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid

[113] FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics, FDA (Sept. 10, 2013); *see also* FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death, FDA (Mar. 22, 2016).

[114] CDC Guideline at 21.

[115] *Id.* at 2.

prescriptions from multiple sources, or theft. This publication is still available online.[116]

c. Non-Defendant Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

d. Janssen reviewed, edited, approved, and distributed a patient education guide entitled Finding Relief Pain Management for Older Adults (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

e. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated." [117]

[116] APF, Treatment Options, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

[117] Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last modified July 2, 2015).

f. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claims that less than 1 % of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction." [118]

g. Consistent with the Manufacturer Defendants' published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen, and Cephalon minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

h. Sales representatives for Actavis and Janssen promoted their drugs as having "steady-state" properties with the intent and expectation that prescribers would understand this to mean that their drugs caused less of a rush or a feeling of euphoria, which can trigger abuse and addiction.

i. Non-Defendant Endo actively promoted its reformulated Opana ER on the basis that it was "designed to be crush-resistant," suggesting both (a) that Endo had succeeded in making the drug harder to adulterate, and (b) that it was less addictive, in consequence. In fact, however, Endo knew that "the clinical significance of INTAC Technology or its impact on abuse/misuse has not been established for Opana ER" and that Opana ER

[118] APF, Policymaker's Guide, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (accessed July 12, 2018)

could still be ground and cut into small pieces by those looking to abuse the drug.

j. Janssen denied that Nucynta ER was an opioid and claimed that it was not addictive.

k. Purdue claimed that its opioids were not favored by addicts and did not produce a buzz, all of which falsely suggested that its opioids were less likely to be abused or addictive.

291. In addition to denying or minimizing the risk of addiction and abuse generally, Defendants also falsely claimed that their particular drugs were safer, less addictive, and less likely to be abused or diverted than their competitors' or predecessor drugs. In making these claims, Defendants said or implied that because their drug had a "steady-state" and did not produce peaks and valleys, which cause drug-seeking behavior—either to obtain the high or avoid the low—it was less likely to be abused or addicting.[119]

292. Further, rather than honestly disclose the risk of addiction, Defendants, and the third parties they directed and assisted and whose materials they distributed, attempted to portray those who were concerned about addiction as unfairly denying treatment to needy patients. To increase pressure on doctors to prescribe chronic opioid therapy, Defendants turned the tables; it was doctors who fail to treat their patients' chronic pains with opioids—not doctors who cause their patients to become addicted to opioids—who are failing their patients (and subject to discipline). Defendants and their third-party allies claimed that purportedly overblown worries about addiction cause pain to be under-treated and opioids to be over-regulated and under-prescribed. This mantra

[119] *See* Guidance for Industry, "Abuse-Deterrent Opioids—Evaluation and Labeling," April 2015 (describing requirements for premarket and postmarket studies).

of under-treated pain and under-used drugs reinforced Defendants' messages that the risks of addiction and abuse were not significant and were overblown.

293. **"Pseudoaddiction" -**In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, the Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Manufacturer Defendants misrepresented, to doctors and patients, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (i.e. pseudo addiction) - and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

294. To this end, one of Purdue's employees, Dr. David Haddox, invented a phenomenon called "pseudoaddiction." [120] This characterized as "the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management."[121] In other words, people on prescription opioids who exhibited classic signs of addiction— for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—were not addicted, but rather simply suffering from under-treatment of their pain. KOL Dr. Portenoy popularized the term.

295. Examples of the false, misleading, deceptive, and unfair statements regarding pseudoaddiction include:

[120] [119]David E. Weissman and J. David Haddox, *Opioid pseudoaddiction—an iatrogenic syndrome*, 36(3) Pain 363-66 (Mar. 1989), https://www.ncbi.nlm.nih.gov/pubmed/2710565. ("Iatrogenic" describes a condition induced by medical treatment.

[121] Id.

a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct physicians that aberrant behaviors like self-escalation of doses constituted "pseudoaddiction."

b. Cephalon sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of "pseudoaddiction." Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists.

c. From 2009 to 2011 Janssen's website, *Let's Talk Pain*, stated that "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated" and that "[p]seudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." (emphasis added).

d. Non-Defendant Endo distributed copies of a book by KOL Dr. Lynn Webster entitled *Avoiding Opioid Abuse While Managing Pain* (2007). Endo's internal planning documents describe the purpose of distributing this book as to "[i]ncrease the breadth and depth of the Opana ER prescriber base." The book claims that when faced with signs of aberrant behavior, the doctor should regard it as "pseudoaddiction" and thus, increasing the dose *in most cases. . . Should be the clinician's first response*." (emphasis added).

e. Non-defendant Endo spent $246,620 to buy copies of FSMB's *Responsible Opioid Prescribing* (2007), which was distributed by Endo's sales force. This book asserted that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction."

f. Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described "pseudoaddiction" as a concept that "emerged in the literature to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

g. Purdue distributed to physicians, at least as of November 2006, and posted on its unbranded website, *Partners Against Pain*, a pamphlet copyrighted 2005 and titled *Clinical Issues in Opioid Prescribing*. This pamphlet included a list of conduct, including "illicit drug use and deception" it defined as indicative of "pseudoaddiction" or untreated pain. It also states: "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when *pain is undertreated*. . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be *distinguished from true addiction* in that the behaviors resolve when the pain is effectively treated." (emphasis added.)

h. Purdue sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name, "demanding

or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction." Purdue also spent over $100,000 to support distribution of the book.

i. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which states: "Pseudo-addiction describes patient behaviors that may occur when *pain is undertreated*. . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated."[122] (Emphasis added.)

296. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already addicted patients.

297. **Falsse Information Risk Screening Tools** -While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Manufacturing Defendants assert that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage that risk by using screening tools or questionnaires. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors can then more closely

[122] APF, Policymaker's Guide, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last accessed Jul. 12, 2018)

298. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids.

299. The Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

a. Documents from a 2010 sales training indicate that Actavis trained its sales force that prescribers can use risk screening tools to limit the development of addiction.

b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."[123]

c. Non-Defendant Endo paid for a 2007 supplement[124] available for continuing education credit in the Journal of Family Practice. This publication, titled Pain Management Dilemmas in Primary Care: Use of Opioids, recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain, and advised that patients at high risk of

[123] Am. Pam Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, Treatment Options], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

[124] The Medical Journal, *The Lancet found that all of the supplement papers it received failed peer-review. Editorial, "The Perils of Journal and Supplement Publishing,"* 375 The Lancet 9712 (347) 2010.

addiction could safely (e.g., without becoming addicted) receive chronic opioid therapy using a “maximally structured approach” involving toxicology screens and pill counts.

d. Purdue, upon information and belief, sponsored a 2011 webinar, Managing Patient's Opioid Use: Balancing the Need and Risk, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

e. Purdue’s unbranded website, In the Face of Pain (inthefaceofpain.com) states that policies that “restrict[] access to patients with pain who also have a history of substance abuse” and “requiring special government-issued prescription forms for the only medications that are capable of relieving pain that is severe” are “at odds with” best medical practices.[125]

f. In 2011, Purdue published a prescriber and law enforcement education pamphlet titled *Providing Relief, Preventing Abuse*, which deceptively portrayed the signs—and therefore the prevalence— of addiction. However, Purdue knew, as described above, that OxyContin was used non-medically by injection less than less than 17% of the time. Yet, *Providing Relief, Preventing*

[125] See In the Face of Pain Fact Sheet: Protecting Access to Pain Treatment, Purdue Pharma L.P. (Resources verified Mar. 2012),www.inthefaceofpain.com/content/uploads/2011/12/factsheet_ProtectingAccess.pdf (deactivated).

Abuse prominently listed side effects of injection like skin popping and track marks as "Indications of Possible Drug Abuse"— downplaying much more prevalent signs of addiction associated with OxyContin use such as asking for early refills, making it seem as if addiction only occurs when opioids are taken illicitly.

g. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients - and not opioids - are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

h. Purdue and Cephalon sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid agreements between doctors and patients can "ensure that you take the opioid as prescribed" and counseled patients that opioids "give [pain patients] a quality of life we deserve."

300. The 2016 CDC Guideline confirms the falsity of these claims. The Guideline explains that there are no studies assessing the effectiveness of risk mitigation strategies "for improving outcomes related to overdose, addiction, abuse or misuse." [126]

[126] Deborah Dowell *et al*., CDC Guideline for Prescribing Opioids for Chronic Pain-United States, 2016, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm (accessed July 13, 2018).

301. **False Information Related to Withdrawal** - Defendants and their third-party allies promoted the false and misleading messages below with the intent and expectation that, by misrepresenting the difficulty of withdrawing from opioids, prescribers and patients would be more likely to start chronic opioid therapy and would fail to recognize the actual risk of addiction.

302. In an effort to underplay the risk and impact of addiction, Defendants and their third- party allies frequently claim that, while patients become "physically" dependent on opioids, physical dependence can be addressed by gradually tapering patients' doses to avoid the adverse effects of withdrawal. They fail to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—effects that also make it less likely that patients will be able to stop using the drugs.

303. In reality, withdrawal is prevalent in patients after more than a few weeks of therapy. Common symptoms of withdrawal include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, and pain. Some symptoms may persist for months, or even years, after a complete withdrawal from opioids, depending on how long the patient had been using opioids. Withdrawal symptoms trigger a feedback loop that drives patients to seek opioids, contributing to addiction.

304. Each of the publications and statements below falsely states or suggests that withdrawal from opioids was not a problem and they should not be hesitant about prescribing or using opioids:

a. Documents from a 2010 sales training indicate that Actavis trained its sales force that discontinuing opioid therapy can be handled "simply" and that it can be done at home. Actavis's sales representative training

claimed opioid withdrawal would take only a week, even in addicted patients.

b. A CME sponsored by Endo, titled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days.

c. A Janssen PowerPoint presentation used for training its sales representatives titled "Selling Nucynta ER" indicates that the "low incidence of withdrawal symptoms" is a "core message" for its sales force. This message is repeated in numerous Janssen training materials between 2009 and 2011. The studies supporting this claim did not describe withdrawal symptoms in patients taking Nucynta ER beyond 90 days or at high doses and would therefore not be representative of withdrawal symptoms in the chronic pain population. Patients on opioid therapy long-term and at high doses will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms, Janssen relied upon a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use; Janssen knew or should have known that these symptoms peak earlier than that for most patients. Relying on data after that initial window painted a misleading picture of the likelihood and severity of withdrawal associated with chronic opioid therapy. Janssen also knew or should have known that the patients involved in the study were not on the drug long enough to develop rates

of withdrawal symptoms comparable to rates of withdrawal suffered by patients who use opioids for chronic pain—the use for which Janssen promoted Nucynta ER.

d. Janssen sales representatives told prescribers that patients on Janssen's drugs were less susceptible to withdrawal than those on other opioids.

e. Purdue sponsored *APF's A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany cessation of use.[127]

f. Purdue sales representatives told prescribers that the effects of withdrawal from opioid use can be successfully managed.

g. Purdue sales representatives told prescribers that the potential for withdrawal on Butrans was low due to Butrans's low potency and its extended release mechanism.

305. **False Claims that Increased Dosing Posed no Significant Increased Risks** Each of the following misrepresentations was created with the intent and expectation that, by misrepresenting and failing to disclose the known risks of high dose opioids, prescribers and patients would be more likely to continue to prescribe and use opioids, even when they were not effective in reducing patients' pain, and not to discontinue opioids even when tolerance required them to reach even higher doses.

[127] APF, Policymaker's Guide, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (accessed July 12, 2018)

306. Defendants and their third-party allies claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high," suggesting that patients would eventually reach a stable, effective dose. Each of Defendants' claims also omitted warnings of increased adverse effects that occur at higher doses, and misleadingly suggested that there was no greater risk to higher dose opioid therapy.

307. These claims are false. Patients receiving high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer an overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The FDA has itself acknowledged that available data suggest a relationship between increased doses and the risk of adverse effects. Moreover, it is harder for patients to terminate use of higher-dose opioids without severe withdrawal effects, which contributes to a cycle of continued use, even when the drugs provide no pain relief and are causing harm—the signs of addiction.

308. Each of the following claims suggests that high-dose opioid therapy is safe:

a. Documents from a 2010 sales training indicate that Actavis trained its sales force that "individualization" of opioid therapy depended on increasing doses "until patient reports adequate analgesia" and to "set dose levels on [the] basis of patient need, not on [a] predetermined maximal dose." Actavis further counseled its sales representatives that

the reasons some physicians had for not increasing doses indefinitely were simply a matter of physician "comfort level," which could be overcome or used as a tool to induce them to switch to Actavis's opioid, Kadian.

b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claimed that some patients "need" a larger dose of their opioid, regardless of the dose currently prescribed.[128]

c. Cephalon sponsored a CME written by KOL Dr. Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non- opioid analgesics and combination opioids that include aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations.

d. Cephalon sales representatives assured prescribers that opioids were safe, even at high doses.

e. Nonj-Defendant Endo sponsored a website, painknowledge.com, through APF and NIPC, which, in 2009, claimed that opioids may be increased until "you are on the right dose of medication for your pain," and once that occurred, further dose increases would not occur. Endo funded the site, which was a part of Endo's marketing plan, and tracked visitors to it.

[128] APF, Treatment Options, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

f. Non-Defendant Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics.* In Q&A format, it asked: "If I take the opioid now, will it work later when I really need it?" The response was: "The dose can be increased . . . . You won't 'run out' of pain relief."

g. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved an its sales force distributed. This guide listed dose limitations as "disadvantages" of other pain medicines and omitted any discussion of risks of increased doses of opioids. The publication also falsely claimed that it is a "myth" that "opioid doses have to be bigger over time."

h. Purdue's *In the Face of Pain* website, along with initiatives of APF, promoted the notion that if a patient's doctor does not prescribe them what—in their view—is a sufficient dose of opioids, they should find another doctor who will. In so doing, Purdue exerted undue, unfair, and improper influence over prescribers who face pressure to accede to the resulting demands.

i. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which taught that dose escalations are "sometimes necessary," even indefinitely high ones. This suggested that high dose

opioids are safe and appropriate and did not disclose the risks from high dose opioids. This publication is still available online.[129]

j. Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which taught patients that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The guide also claimed that some patients "need" a larger dose of the drug, regardless of the dose currently prescribed. [130] This language fails to disclose heightened risks at elevated doses.

k. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013. The CME, Overview of Management Options, was edited by KOL Dr. Russell Portenoy, among others, and taught that other drugs, but not opioids, are unsafe at high doses. The 2013 version is still available for CME credit.

l. Purdue sales representatives told prescribers that opioids were just as effective for treating patients long-term and omitted any discussion that increased tolerance would require increasing, and increasingly dangerous, doses.

309. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants' representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established" while the

---

[129] APF, Policymaker's Guide, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last accessed Jul. 12, 2018)

[130] APF, Treatment Options, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

"risks for serious harms related to opioid therapy increase at higher opioid dosage."[131] More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages.[132] The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression, and death at higher dosages.[133] That is why the CDC advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.[134]

C. Defendants Minimized Adverse Effects of Opioids and Overstated Risks of Alternatives

310. Each of the following misrepresentations was created with the intent and expectation that, by omitting the known, serious risks of chronic opioid therapy, including the risks of addiction, abuse, overdose, and death, and emphasizing or exaggerating risks of competing products, prescribers and patients would be more likely to choose opioids. Defendants and their third-party allies routinely ignored the risks of chronic opioid therapy. These include (beyond the risks associated with misuse, abuse, and addiction): hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[135] hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal

[131] 2016 CDC Guideline, supra, at ft. note 30.
[132] *ld.*.
[133] *ld.*
[134] *ld.*.
[135] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (disorders frequently coexisting with chronic pain conditions).[136]

311. Despite these serious risks, Defendants asserted, or implied, that opioids were appropriate first-line treatments and safer than alternative treatments, including NSAIDs such as ibuprofen (Advil, Motrin) or naproxen (Aleve). While NSAIDs can pose significant gastrointestinal, renal, and cardiac risks, particularly for elderly patients, Defendants' exaggerated descriptions of those risks were deceptive in themselves, and also made their omissions regarding the risks of opioids all the more striking and misleading. Defendants and their third-party allies described over-the-counter NSAIDs as life-threatening and falsely asserted that they were responsible for 10,000-20,000 deaths annually (more than opioids), when in reality the number is closer to 3,200. This description of NSAIDs starkly contrasted with their representation of opioids, for which the listed risks were nausea, constipation, and sleepiness (but not addiction, overdose, or death). Compared with NSAIDs, opioids are responsible for roughly four times as many fatalities annually.

312. As with the preceding misrepresentations, Defendants' false and misleading claims regarding the comparative risks of NSAIDs and opioids had the effect of shifting the balance of opioids' risks and purported benefits. While opioid prescriptions have exploded over the past two decades, the use of NSAIDs has declined during that same time.

[136] Several of these risks do appear in the FDA-mandated warnings. *See, e.g.*, the August 13, 2015 OxyContin Label, Section 6.2, identifying adverse reactions including: "abuse, addiction … death, … hyperalgesia, hypogonadism . . . mood altered . . . overdose, palpitations (in the context of withdrawal), seizures, suicidal attempt, suicidal ideation, syndrome of inappropriate antidiuretic hormone secretion, and urticaria [hives]."

313. Each of the following reflects Defendants' deceptive claims and omissions about the risks of opioids, including in comparison to NSAIDs:

1. Documents from a 2010 sales training indicate that Actavis trained its sales force that the ability to escalate doses during long-term opioid therapy, without hitting a dose ceiling, made opioid use safer than other forms of therapy that had defined maximum doses, such as acetaminophen or NSAIDs.
2. Actavis also trained physician-speakers that "maintenance therapy with opioids can be safer than long-term use of other analgesics," including NSAIDs, for older persons.
3. Kadian sales representatives told Charleston County prescribers that NSAIDs were more toxic than opioids.
4. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain.[137] The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.[138]

[137] Am. Pam Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, Treatment Options], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.
[138] *Id*.

5. Cephalon sales representatives told County prescribers that NSAIDs were more toxic than Cephalon's opioids.
6. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This publication described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness," which the brochure claims will go away, and constipation.
7. Janssen sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines. Janssen's label for Duragesic, however, states that use with benzodiazepines "may cause respiratory depression, [low blood pressure], and profound sedation or potentially result in coma. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids.

8. Janssen sales representatives told prescribers that Nucynta was not an opioid, making it a good choice for chronic pain patients who previously were unable to continue opioid therapy due to excessive side effects. This statement was misleading because Nucynta is, in fact, an opioid and has the same effects as other opioids.

D. The Manufacturer Defendants made materially deceptive statements and fraudulently concealed material facts and misconduct.

314. **Defendant Janssen** made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic noncancer pain and that opioids improve quality of life, while concealing contrary data;

c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through

internet sites over which Janssen exercised final editorial control and approval;

d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of

addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic noncancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

n. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing.

315. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic noncancer pain in conjunction with Cephalon's potent rapid-onset opioids;

e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

j. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing and speakers' bureau events.

316. **Defendant Actavis** made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Making deceptive statements concerning the use of opioids to treat chronic non- cancer pain to prescribers through in-person detailing;

b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for

the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data

317. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes. The FDA warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and death - all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

318. At all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and

fraudulent conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Janssen, ran similar websites that masked their own role.

319. Additionally, the Defendants had programs that pushed marketing efforts to those Physicians that prescribed high amounts of opioids. The Defendants had data that showed who as prescribing and where, large amounts of opioids. The Defendants then focused marketing efforts on core prescribers to maintain and grow their contribution and provided incentives to sales staff to continue marketing and increasing sales. As explained below, Defendants were under a duty to report this suspicious activity but intentionally did not and instead blamed the physicians as “bad actors”.

320. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies

did not support. The Manufacturer Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales.

III. THE MANUFACTURER DEFENDANT'S SCHEME SUCCEEDED

A. The Marketing Defendants' dramatically expanded Opioid Prescribing and Use

338. The Marketing Defendants necessarily expected a return on the enormous investment they made, in their deceptive marketing scheme, and worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers (doctors) and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

339. Cephalon, for example, recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated $15 million in sales. By 2002, Actiq sales had increased by 92%, which Cephalon attributed to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists."[139] Actiq became Cephalon's second best-selling drug. By

---

[139] Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm.

the end of 2006, Actiq's sales had exceeded $500 million.[140] Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."[141]

340. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that each of the Marketing Defendants tracked the impact of their marketing efforts to measure their impact in changing doctors' perceptions and prescribing of their drugs. Their purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. They monitored doctors' prescribing before and after detailing visits, and at various levels of detailing intensity, and before and after speaker programs, for instance. Defendants continued and, in many cases, expanded and refined their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances (e.g., the low abuse potential of various Defendants' opioids), and more generally, Defendants' marketing changed prescribers' willingness to prescribe opioids, lead them to prescribe more of their opioids, and persuaded them not to stop prescribing opioids or to switch to "safer" opioids, such as ADF.

342. This success would have come as no surprise. Drug company marketing materially impacts doctors' prescribing behavior.[142] The effects of sales calls on prescribers' behavior is well

[140] Carreyrou, *Narcotic Lollipop*
[141] Id.
[142] *See, e.g.*, P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); *see also* A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000

documented in the literature. One study examined four practices, including visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

343. Marketing Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.[143] These results are directly due to the Marketing Defendants' fraudulent marketing campaign focused on several misrepresentations.

344. Thus, both independent studies and Defendants' own tracking confirm that Defendants' marketing scheme dramatically increased their sales.

B. The Marketing Defendants Deception in expanding their market created and fueled the Opioid Epidemic.

345. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic

---

annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

[143] CS Hwang et al., *Prescription Drug Abuse: A National Survey of Primary Care Physicians*, 175 JAMA Intern. Med. 302 (2014), doi: 10.1001/jamainternmed.2014.6520, https://www.ncbi.nlm.nih.gov/pubmed/25485657.

exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[144] It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

346. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes." The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications." [145]

347. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

---

[144] Theodore J. Cicero et al., *Relationship Between Therapeutic Use and Abuse of Opioid Analgesics in Rural, Suburban, and Urban Locations in the United States*, 16 Pharmacopidemiology and Drug Safety, 827-40 (2007), doi: 10.1002/pds.1452, https://www.cdhs.udel.edu/content-sub-site/Documents/Publications/Relationship%20Between%20Therapeutic%20Use%20and%20Abuse%20of %20Opioid%20Analgesics.pdf.

[145] *See* Califf et al., supra n. 11.

IV. DEFENDANTS BREACHED THEIR DUTY TO PREVENT UNLAWFUL DISTRIBUTION OF OPIOIDS

A. All Defendants' have a Duty to guard against, and report Unlawful diversion and to report and prevent suspicious orders

348. Multiple sources impose duties on Defendants with respect to the supply of opioids, including the common law duty to exercise reasonable care. Defendants have specific duties under federal law as well. Each Defendant was required to register with the DEA, pursuant to the CSA. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Defendant is a "registrant" of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

349. Each Defendant has an affirmative duty under federal law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that "requirements" of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1).

350. Federal regulations impose a non-delegable duty upon requirements to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

351. "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. See 21 CFR 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a

normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry.

352. In addition to reporting all suspicious orders, the Distributor Defendants must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the recipient can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. Id.

353. These prescription drugs are regulated for the purpose of providing a "closed" system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[146]

354. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.

[146] *See* 1970 U.S.C.C.A.N. 4566, 4571-72

B. All Defendants were aware of and acknowledged their duty to prevent diversion and to report and take steps to halt suspicious orders

355 The reason for the reporting rules is to create a "closed" system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors' obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.

356. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

C. Defendants Kept Careful Track of Prescribing Data and Kew About Suspicious Orders and Prescribers

357. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential Automation of Reports and Consolidated Orders System (ARCOS) database. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor and Marketing Defendants but has not been disclosed to the public.

358. Publicly available information confirms that Distributor and Marketing Defendants funneled far more opioids into communities across the United States than could have

been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to Distributor and Marketing Defendants, would have alerted them to potentially suspicious orders of opioids.

359. This information includes the following facts:

1. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

2. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;

3. manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion;

4. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and

5. Manufacturer Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

360. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids-even the wider market for chronic pain.

361. At all relevant times, the Defendants were in possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, Iqvia, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the "Data Vendors").

362. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[147] The "know your customer" questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

363. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors'

---

[147] *Suggested Questions a Distributor should ask prior to shipping controlled substances*, DEA, https://www.deadiversion.usdoj.gov/mtgs/pharm industry/14th pharm/levinl ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq. *Pharmaceutical Product Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC, https://www.mcguirewoods.com/news-resources/publications/lifesciences/product diversion beyond pdma.pdf

information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors' sales, and to compare and analyze market share information.[148]

364. IMS, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.[149]

365. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.[150]

366. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances. [151] Defendants were, therefore, collectively aware of the suspicious orders that flowed from their facilities.

[148] A Verispan representative testified that the Supply Chain Defendants use the prescribing information to "drive market share." *Sorrell v. IMS Health Inc.*, 2011 WL 661712, *9-10 (Feb. 22, 2011).

[149] Paul Kallukaran & Jerry Kagan, *Data Mining at IMS HEALTH: How we Turned a Mountain of Data into a Few Information-rich Molehills*, http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.198.349&rep=rep1&type=pdf, Figure 2 at p. 3 (last accessed April 28, 2018).

[150] *Sorrell v. IMS Health Inc.*, 2011 WL 705207, at *467-471 (Feb. 22, 2011).

[151] In *Sorrell*, expert Eugene "Mick" Kolassa testified, on behalf of the Data Vender, that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians

367. Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. As described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[152] and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders, all for failure to report suspicious orders.[153]

368. Sales representatives were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

> Actions have consequences - so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

369. Moreover, Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get

[152] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.
[153] *Id.*

prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative.[154] In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."[155]

370. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]"[156]She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report."[157] This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

[154] *Pain Killer*, supra n. 34 at 298-300

[155] *Id*. Joint Appendix in *Sorrell v. IMS Health*, 2011 WL 687134, at *204 (Feb. 22, 2011).

[156] Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drug maker knew*, LOS ANGELES TIMES (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.

[157] Id.

371. A Kadian prescriber deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. Kadian's prescriber guide is full of disclaimers that Actavis has not done any studies on the topic and that the guide is "only intended to assist you in forming your own conclusion." However, the guide includes the following statements: 1) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and 2) "KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." (p. 1-2). The guide is copyrighted by Actavis in 2007, before Actavis officially purchased Kadian from Alpharma.[158]

372. Defendants' obligation to report suspicious prescribing ran head on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers, but not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement, nor to report those doctors who drove Defendants' sales.

373. Defendants purchased data from IMS (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors' sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

374. For example, at a national sales meeting presentation in 2011, Actavis pressed itssales representatives to focus on its high prescribers: "To meet and exceed our quota, we must

[158] ACTAVIS0947868 (09/17/2007).

continue to get Kadian scripts from our loyalists. MCOs will continue to manage the pain products more closely. We MUST have new patient starts or we will fall back into 'the big leak'. We need to fill the bucket faster than it leaks." "The selling message should reflect the opportunity and prescribing preferences of each account. High Kadian Writers / Protect and Grow/ Grow = New Patient Starts and Conversions." (pg 13). In an example of how new patients + a high volume physician can impact performance: "102% of quota was achieved by just one high volume physician initiating Kadian on 2-3 new patients per week."[159]The same is true for other Defendants. [160]Teva directed its sales representatives to make a "minimum of seven Fentora calls per day" and focus "on high prescribers to maintain and grow their contribution." Another chart showed Cephalon ensured that the majority highest- volume or "core prescribers," were detailed at least five times in ten months.

375. This focus on marketing to the highest prescribers had two impacts. First, it demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

377. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Marketing Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the doctor: "The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon

[159] ACTAVIS0969604
[160] TEVA_CH_00002233

this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."[161]

378. But given the closeness with which they monitored prescribing patterns through IMS Health data, the Defendants either knew or chose not to know of the obvious drug diversions. In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino's clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

379. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Marketing Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

D. The Distributor Defendants have a duty under federal law to guard against and report unlawful diversion and to report and prevent suspicious orders

380. The Distributor Defendants owe a duty under federal law (21 U.S.C. § 823, 21 CFR 1301.74) to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted.

[161] Pain Killer, supra n. 34 at 179.

381. The sheer volume of prescription opioids distributed to pharmacies in various areas, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted, was excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[162]

382. The Distributor Defendants failed to report "suspicious orders," or which the Distributor Defendants knew were likely to be diverted, to the federal authorities, including the DEA.

383. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

E. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

384. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

385. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal law.

---

[162] *Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy*, Nos. 219 and 5195, 77 Fed. Reg. 62,316, 62,322 (2012)).

386. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.[163]

387. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes

388. Each Distributor Defendant repeatedly and purposefully breached its duties under state and federal law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes.

389. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality and social and financial costs borne by, among others, individuals, families and Independent Emergency Room Physicians.

390. The Distributor Defendants' intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid epidemic and causing the damages alleged herein.

391. Opioids are a controlled substance. These "Schedule II" drugs are controlled substances with a "high potential for abuse." 21 U.S.C. §§ 812(b), 812(2)(A)-(C).

392. The Manufacturer Defendants created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties

[163] *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

393. Each Distributor Defendant was required to register with the DEA, pursuant to the federal Controlled Substance Act. See 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme.

394. Each Distributor Defendant has an affirmative duty under federal law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1).

395. Federal regulations impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant distributor 1 shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

396. "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. See 21 CFR 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter, and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's

responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

397. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. S*ee Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enft Admin. July 3, 2007); Masters Pharmaceutical, Inc. v. Drug Enforcement Administration, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. Id. 150.

398. These prescription drugs are regulated for the purpose of providing a "closed" system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.[164]

399. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.[165]

---

[164] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.

[165] Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm .• Inc.* v. *U.S. Drug Enft. Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at *22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)--now known as the Healthcare Distribution Alliance (HDA)--is a national, not-for-profit trade association that represents the nation's
primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See*

400. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[166]

401. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.[167]

402. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, in addition to reporting suspicious orders, has a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into

generally HDA, *About,* https://www.healthcaredistribution.org/about (accessed July 12, 2018). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Corporation and Wa1mart. *See generally* NACDS, *Mission,* https://www.nacds.org/about/mission/ (accessed July 12, 2018).

[166] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."), *filed in Cardinal Health, Inc.* v. *Holder,* No. I : 12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

[167] *See* Brief for HDMA and NACDS, *supra* note 85, 2016 WL 1321983, at *4 ("[R]egulations ... in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).').

other than legitimate medical, scientific, and industrial channels."[168] The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[169] The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

403. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.[170] This letter reminds the Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances. "[171] Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[172]

404. The Distributor Defendants have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs but undertake such efforts as responsible members of society.

405. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution

---

[168] *See* Rannazzisi Letter ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently *faces.*"),*filed in Cardinal Health, Inc.* v. *Holder,* No. I : 12-cv-00185-RBW (D.D.C. Feb. 10,2012), ECF No. 14-51.
[169] *Id*. at 1.
[170] *Id*. at 2.
[171] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enrt
Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc.* v. *Holder*, No. 1:12-cv- 00 185-RBW (D.D.C. Feb. 10,2012) ,ECF No. 14-8.
[172] *Id*.

Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.[173]

406. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers from which Defendants knew prescription opioids were likely to be diverted.

407. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

408. Each Distributor Defendant owes a duty under federal law to investigate and refuse suspicious orders of prescription opioids.

409. Each Distributor Defendant owes a duty under federal law to report suspicious orders of prescription opioids.

410. Each Distributor Defendant owes a duty under federal law to prevent the diversion of prescription opioids into illicit markets throughout the United States.

[173] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

411. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

412. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality and the damages caused thereby.

413. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.[174]

414. The sheer volume of prescription opioids distributed to pharmacies in various areas, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted, was excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[175]

415. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

416. The Marketing Defendants engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The Washington Post has described the

[174] *See* Rannazzisi Decl. ¶10, filed in *Cardinal Health, Inc.* v. *Holder,* No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

[175] *Masters Pharmaceuticals, Inc.,* 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (*citing Holiday CVS, L.L.C., d/b/a CVs/Pharmacy Nos.* 219 *and* 5195,77 Fed. Reg. 62,316, 62,322 (2012)).

practice as industry-wide, and the Healthcare Distribution Alliance ("HDA") includes a "Contracts and Chargebacks Working Group," suggesting a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)." The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants," meaning pharmacies or other dispensaries, such as hospitals. Marketing Defendants buy data from pharmacies as well. This exchange of information, upon information, and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

417. The interaction and length of the relationships between and among the Marketing and Distributor Defendants reflect a deep level of interaction and cooperation between two groups in a tightly knit industry. The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

418. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperation

419. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Marketing and Distributor Defendants did this through their participation in the PCF and HDA

420. The Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with their reporting obligations.

421. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

422. None of the Defendants reported suspicious orders and the flow of opioids continued unimpeded.

F. **The Distributor Defendants failed to report "suspicious orders," or which the Distributor Defendants knew were likely to be diverted, to the federal authorities, including the DEA.**

423. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted.

424. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

425. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal law.

426. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.[176]

427. Publicly available information confirms that Distributor and Manufacturing Defendants funneled far more opioids into communities across the United States than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders.

428. This information includes the following facts:

a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;

c. manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion;

d. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and

e. Marketing Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

429. This information shows Defendants were on notice of the problems of abuse and diversion and that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids-even the wider market for chronic pain.

430. The federal laws at issue here are public safety laws.

[176] *See Cardinal Health, Inc.* v. *Holder,* 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

431. The Distributor Defendants had a duty under various state and federal laws to ensure opioids were not diverted and to report any suspicion of diversion. The Defendants further owed a duty of care to individuals and to physicians to present truthful information about addiction. Defendants breached those duties as show above.

432. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by federal law which are required to legally acquire and maintain a license to distribute prescription opiates.

433. The Distributor Defendants acted with actual malice in breaching their duties, i.e., they have acted with a conscious disregard for the rights and safety of other persons, including misleading Independent Emergency Room Physicians with the goal of increasing use of opioids, and said actions caused significant harm and have a great probability of causing additional substantial harm.

434. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

G. **Distributor Defendants Have Sought to Avoid and Have Misrepresented their Compliance with Their Legal Duties**.

435. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under federal law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public.

436. Wholesale Distributor McKesson has recently been forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[177] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[178] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distribution Centers."

437. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.[179] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor

---

[177] *See* Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17,2017), https://www.justice.gov/opa/press-release/file/928476/download (accessed July 12, 2018).
[178] *Id*. at 4.
[179] *Id*. at 4.

its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so.[180] The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."[181] As a result of these violations, McKesson was fined and required to pay to the United States $150,000,000.[182]

438. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

439. Because of the Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.[183] The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76

---

[180] *Id.*
[181] *ld.; see also* Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter 2017 Settlement Agreement and Release] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DBA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), https://www.justice.gov/opa/press-release/file/928471/download (accessed July 12, 2018).
[182] *See Id*. at 6.
[183] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf (last accessed July 12, 2018)

actions involving orders to show cause and 41 actions involving intermediate suspension orders.[184] These actions include the following:

a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22,2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydro cod one;

c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydro cod one;

e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas

---

[184] *Id.*

Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA',) with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301. 74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23,2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

440. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[185]

[185] Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control,* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.57dd9e32043c (accessed July 13, 2018); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis,* Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-

441. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

442. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[186] Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results.

443. Similarly, Defendant McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[187] Again, given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

---

a05d3c21f7cf_story.html?utm_term=.61f36a18c2c9, (accessed July 13, 2018); Eric Eyre, *DEA Agent:"We Had No Leadership" in WV Amid Flood of Pain Pills,* Charleston Gazette-Mail, Feb. IS, 2017, https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html, (accessed July 13, 2018).

[186] Lenny Bernstein *et al*., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.6a8f1d95aeae (accessed July 13, 2018).

[187] Scott Higham *et al*., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse,* Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.e3bb235ff695 (accessed July 13, 2018).

444. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts.

445. Meanwhile, the opioid epidemic rages unabated in the United States.

446. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

447. The wrongful actions and omissions of the Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's racketeering allegations below.

448. The Distributor Defendants have abandoned their duties imposed under federal law, taken advantage of a lack of DEA law enforcement, and abused the privilege of distributing controlled substances.

H. The Manufacturer Defendants Have Unlawfully Failed to Prevent Diversion and Monitor, Report and Prevent Suspicious Orders.

449. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under federal law.

450. Like the Distributor Defendants, the Manufacturer Defendants were required to register with the DEA to manufacture schedule II-controlled substances, like prescription opioids.

See 21 U.S.C. § 823(a). A requirement of such registration is the: maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or IT compounded there from into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes. 21 USCA § 823(a)(1) (emphasis added).

451. Additionally, as "registrants" under Section 823, the Manufacturer Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances: The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 C.F.R. § 1301.74. See also 21 C.F.R. § 1301.02 ("Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21 C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958)." Like the Distributor Defendants, the Manufacture Defendants breached these duties.

452. The Manufacturing Defendants created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties

453. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew - just as the Distributor Defendants knew - the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

454. Federal statutes and regulations are clear: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose ... suspicious orders of controlled substances" and to maintain "effective controls against diversion." 21 C.F.R. § 1301.74; 21 USCA § 823(a)(I).

455. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating record keeping requirements.[188]

[188] *See* Press Release, U.S. Dep't of Justice, Mallin
ckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations(July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders (accessed July 12, 2018).

456. In the press release accompanying the settlement, the Department of Justice stated: Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone .... Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. ... "Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands .... "[189]

457. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances - orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[190]

458. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[191]

[189] *Id.*
[190] *Id.*
[191] Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, pic. and its subsidiary Mallinckrodt, LLC (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt (accessed July 12, 2018) MOA").

459. The 2017 Non-Defendant Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer: With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C,F .R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:

a. Conduct adequate due diligence of its customers;

b. Detect and report to the DEA orders of unusual size and frequency;

c. Detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27,2006 and December 27, 2007:

   i. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,

   ii. orders that purchased a disproportionate amount of substance which is most often abused compared to other products, and

   iii. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;

d. Use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to

certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

e. Take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[192]

450. Non-Defendant Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) ... [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[193]

451. Non-Defendant Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to "downstream" registrants." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[194]

[192] 2017 Mallinckrodt MOA at p. 2-3.
[193] *Id*. at 3-4.
[194] *Id*. at 5.

452. The same duties imposed by federal law on Non-Defendant Mallinckrodt were imposed upon all Manufacturer Defendants.

453. The same business practices utilized by Non-Defendant Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Manufacturer Defendants.

454. Through, *inter alia*, the charge back data, the Manufacturer Defendants could monitor suspicious orders of opioids.

455. The Manufacturer Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal law.

456. The Manufacturer Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

457. The Manufacturer Defendants have misrepresented their compliance with federal law.

458. The wrongful actions and omissions of the Manufacturer Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's racketeering allegations below.

459. The Manufacturer Defendants' actions and omissions in failing to effective prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids throughout the United States and South Carolina.

460. Non-Defendant Insys was co-founded in 2002 by Dr. John Kapoor, a serial pharmaceutical industry entrepreneur "known for applying aggressive marketing tactics and sharp price increases on older drugs."[195]

461. In 2012, Non-Defendant Insys received U.S. Food and Drug Administration approval for Subsys, a fentanyl sublingual spray product designed to treat breakthrough cancer pain. However, Insys encountered significant obstacles due to insurers employing a process known as prior authorization. Prior authorization prevents the over prescription and abuse of powerful and expensive drugs. The prior authorization process requires "additional approval from an insurer or its pharmacy benefit manager before dispensing…" and may also impose step therapy which requires beneficiaries to first use less expensive medications before moving on to a more expensive approach.[196]

462. Non-Defendant Insys circumvented this process by forming a prior authorization unit, known at one point as the Insys Reimbursement Center ("IRC"), to facilitate the process using aggressive and likely illegal marketing techniques. Insys published education articles that praised their products' non-addictive nature; and funded patient advocacy groups who unknowingly promoted Insys' agenda of raising the profile of pain so that drugs could be prescribed to treat it. Furthermore, Insys' former sales representatives, motivated by corporate greed, paid

[195] U.S. senate Homeland Security & Governmental Affairs Committee, Insys Therapeutics and the Systemic Manipulation of Prior Authorization (quoting Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids, Wall Street Journal) (Nov. 22, 2016) (www.wsj.com/articles/fentanylbillionaire- comes-under-fire-as-death-toll-mounts-from-prescription-opioids-1479830968) (accessed July 13, 2018).
[196] Senate Permanent Subcommittee on Investigations, Combatting the Opioid Epidemic: A Review of Anti- Abuse Efforts in Medicare and Private Health Insurance Systems; see also Department of Health and Human Services, Centers for Medicare & Medicaid Services, How Medicare Prescription Drug Plans & Medicare Advantage Plans with Prescription Drug Coverage Use Pharmacies, Formularies, & Common Coverage Rules

off medical practitioners to prescribe Subsys in spite of any medical need.[197] Insys employees were pressured internally and received significant monetary incentives to increase the rate of prescription approvals.[198]

463. According to a federal indictment and ongoing congressional investigation by Sen. Claire McCaskill, IRC employees pretended to be with doctors' offices and falsified medical histories of patients. The report, acquired by McCaskill's investigators, includes transcripts and an audio recording of employees implementing these techniques in order to obtain authorization from insurers and pharmacy benefit managers. The transcript reveals an Non-Defendant Insys employee pretending to call on behalf of a doctor and inaccurately describes the patient's medical history.[199] For example, Insys employees would create the impression that the patient had cancer, without explicitly saying so, because cancer was a requirement for prior clearance to prescribe Subsys. Insys was warned by a consultant that it lacked needed policies for governing such activities, but the executives failed to implement corrective internal procedures.

464. In a class action law suit against Non-Defendant Insys, it was revealed that management "was aware that only about 10% of prescriptions approved through the Prior Authorization Department were for cancer patients," and an Oregon Department of Justice Investigation found that 78% of preauthorization forms submitted by Insys on behalf of Oregon

[197] Lopez, Linette. "It's been a brutal week for the most shameless company in the opioid crisis-and it's about to get worse," Business Insider, https://nordic.businessinsider.com/opioid-addiction-drugmaker-insys-arrests-justice-department-action-2017- 7/ (accessed July 16, 2018)
[198] Boyd, Roddy. Murder Incorporated: Insys Therapeutics. Part 1. Southern Investigative Reporting Foundation. http://sirf-online.org/2015/12/03/murder-incorporated-the-insys-therapeutics-story/ (accessed July 16, 2018); *see also* Indictment. *United States v. Babich, et al.*, D. Mass. (No. 1;16 CR 10343).
[199] U.S. Senate Homeland Security & Governmental Affairs Committee, Fueling an Epidemic: Insys Therapeutics and the Systematic Manipulation of Prior Authorization, see p. 7-10, available at https://www.documentcloud.org/documents/3987564-REPORT-Fueling-an-Epidemic-Insys-Therapeutics.html (accessed July 16, 2018)

patients were for off-label uses.[200] Physicians are allowed to prescribe medications for indications outside of FDA guidelines if they see fit, but it is illegal for pharmaceutical companies to market a drug for off-label use.

465. In 2008, biopharmaceutical company Cephalon settled with the U.S. Government for425 million in a suit against the company that alleged it marketed drugs for unapproved uses (off-label). The FDA approved the drug only for opioid tolerant cancer patients. According the Oregon settlement and class-action lawsuit, at least three employees involved in sales and/or marketing at Cephalon had moved over to Insys Therapeutics.[201]

466. Additionally, Non-Defendant Insys created a "legal speaker program" which turned out to be a scam. The Justice Department commented on the program and stated:

> The Speaker Programs, which were typically held at high-end restaurants, were ostensibly designed to gather licensed healthcare professionals who had the capacity to prescribe Subsys and educate them about the drug. In truth, the events were usually just a gathering of friends and co-workers, most of whom did not have the ability to prescribe Subsys, and no educational component took place. "Speakers" were paid a fee that ranged from $1,000 to several thousand dollars for attending these dinners. At times, the sign-in sheets for the Speaker Programs were forged so as to make it appear that the programs had an appropriate audience of healthcare professionals.

467. Non-Defendant Insys paid hundreds of thousands of dollars to doctors in exchange for prescribing Subsys and three top prescribers have already been convicted of taking bribes.

---

[200] Gusovsky, Dina. The Pain Killer: A drug Company Putting Profits Above Patients, CNBC (https://www.cnbc.com/2015/11/04/the-deadly-drug-appeal-of-insys-pharmaceuticals.html) (accessed July 16, 2018).
[201] *Id*.

468. Fentanyl products are considered to be the most potent and dangerous opioids on the market and up to 50 times more powerful than heroine.[202]

469. In an internal presentation dated 2012 and entitles, "2013 SUBSYS Brand Plan," Insys identified one of six "key strategic imperatives" as "Mitigate Prior Authorization barriers."[203] On a later slide, the company identified several tasks associated with this effort, including "Build internal [prior authorization] assistance infrastructure," "Establish an internal 1-800 reimbursement assistance hotline," and "Educate field force on [prior authorization] process and facilitation."[204]

470. Additional materials produced by Non-Defendant Insys to the minority staff suggest, however, that Insys did not match these efforts with sufficient compliance processes to prevent fraud and was internally aware of the danger of problematic practices. Specifically, on February 18, 2014, Compliance Implementation Services (CIS)—a healthcare consultant—issued a draft report to Insys titled, "Insys Call Note, Email, & IRC Verbatim Data Audit Report."[205] The introduction to the report explained that "CIS was approached by INSYS' legal representative … on behalf of the Board of Directors for Insys to request that CIS support in

[202] U.S. Department of Justice. Drug Enforcement Administration. A Real Threat to Law Enforcement: Fentanyl. https://www.dea.gov/druginfo/DEA%20Targets%20Fentanyl%20%20A%20Real%20Threat%20to%20Law%20Enforcement%20(2016).pdf

[203] U.S. senate Homeland Security & Governmental Affairs Committee, Insys Therapeutics and the Systemic Manipulation of Prior Authorization (quoting Insys Therapeutics, Inc., 2013 Subsys Brand Plan, 2012 Assessment (2012) (INSYS_HSGAC_00007472)). Available at https://www.hsgac.senate.gov/imo/media/doc/REPORT%20-%20Fueling%20an%20Epidemic%20-%20Insys%20Therapeutics%20and%20the%20Systemic%20Manipulation%20of%20Prior%20Authorization.pdf

[204] *Id*. at INSYS_HSGAC_00007765.

[205] *Id*. (quoting Compliance Implementation Services, Insys Call Note, Email & IRC Verbatim Data Audit Report (Feb. 18, 2014) (INSYS_HSGAC_00007763)).

review of certain communications with Health Care Professionals (HCPs) and INSYS employees, and report how there were being documented."[206] Non-Defendant Insys had expressed concerns "with respect to communications with HCPs by INSYS employees being professional in nature and in alignment with INSYS approved topics regarding off or on-label promotion of an INSYS product, and general adherence to INSYS documentation requirements."[207] An additional concern "stemmed from the lack of monitoring of commercial activities where these types of interactions could occur."[208]

471. Given these issues, Non-Defendant Insys requested that CIS review—in part—"the general communications from the INSYS Reimbursement Center (IRC) to HCPs, their office staff or representatives, as well as health insurance carriers … to ensure they were appropriate in nature with respect to specific uses of SUBSYS, INSYS' commercially marketed product."[209]

472. According to the findings CIS issued, Insys lacked formal policies governing the actions of its prior authorization unit. For example, "[n]o formal and approved policy on appropriate communications between IRC employees and HCPs, their staff, [health care insurers (HCIs)], or patients exists…that governs the support function of obtaining a prior authorization for the use of SUBSYS."[210]

---

[206] *Id*.(citing INSYS_HSGAC_00007765).
[207] *Id*.
[208] *Id*.
[209] *Id*.
[210] *Id*. (citing INSYS_HSGAC_00007770).

473. In addition, the report noted that "there were also gaps in formally approved foundational policies, procedures, and [standard operating procedures] with respect to required processes specifically within the IRC."[211]

474. In fact, "[t]he majority of managerial directives, changes to controlled documents or templates, as well as updates or revisions to processes were not formally approved, documented, and disseminated for use, and were sent informally via email blast."[212]

475. Although four informal standard operating procedures existed with regarded to IRC functions, these documents "lacked a formal review and approval" and failed to "outline appropriately the actions performed within the IRC."[213]

476. The report also explains that Non-Defendant Insys lacked procedures for auditing interactions between IRC employees and outside entities. According to CIS, "no formal, documented, or detailed processes by which IRC representatives' calls via telephone were audited for proper communication with HCPs or HCIs in any fashion [existed] other than random physical review of a call in a very informal and sporadic manner."[214]

477. More broadly, the report notes that "no formal and documented auditing and monitoring or quality control policy, process, or function exists between IRC employee communications and HCPs, HCP staff, HCIs, or patients."[215]

478. At the end of the report, CIS provided a number of recommendations concerning IRC activities. First, CIS suggested that IRC management "formally draft and obtain proper

[211] *Id*. (citing INSYS_HSGAC_00007768).
[212] *Id*. (citing INSYS_HSGAC_00007771).
[213] *Id*. (citing INSYS_HSGAC_00007770).
[214] *Id*. (citing INSYS_HSGAC_00007769).
[215] *Id*. (citing INSYS_HSGAC_00007771).

review and approval of an IRC specific policy detailing the appropriate communications that should occur while performing the IRC associate job functions and interacting with HCPs."[216]

479. Similarly, IRC management was urged to formally draft IRC-specific standard operating procedures "specific to each job function within the IRC," accompanied by "adequate training and understanding of these processes."[217] To ensure compliance with IRC standards, Insys was also directed to create an electronic system to allow management "to monitor both live and anonymously IRC employee communications both incoming and outgoing."[218] Finally, CIS recommended that Insys institute a formal process for revising and updating "IRC documentation used for patient and HCP data."[219]

480. The CIS report concluded by noting, in part, that a review of ten conversations between IRC employees and healthcare providers, office staff, and insurance carriers revealed "that all IRC staff was professional in communication, and in no instance was inaccurate or off-label usage of SUBSYS communicated."[220]

481. Yet within a year of this conclusion, according to the recording transcribed below, an Insys IRC employee appears to have misled a PBM representative regarding the IRC employee's affiliation and the diagnosis applicable to Sarah Fuller. The alleged result, in that case, was death due to inappropriate and excessive Subsys prescriptions.

482. One former Insys sales representative described the motto of this approach to patients as "Start them high and hope they don't die."[221]

---

[216] *Id*. (citing INSYS_HSGAC_00007770).
[217] *Id*. (citing INSYS_HSGAC_00007771).
[218] *Id*.
[219] *Id*.
[220] *Id*. (citing INSYS_HSGAC_00007772).
[221] Amended Class Action Complaint, *Larson v. Insys Therapeutics Inc*. (D. Ariz. Oct. 27, 2014.)

483. Non-Defendant Insys failed to monitor, report, and halt suspicious orders of opioids as required by federal law.

484. Non-Defendant Insys's failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

485. Non-Defendant Insys has misrepresented their compliance with federal law.

486. The wrongful actions and omissions of Insys, which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis harming Plaintiff and the Class.

487. Non-Defendant Insys's actions and omissions in failing to effective prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids throughout the United States and South Carolina.

V. THE NATIONAL RETAIL PHARMACIES WERE ON NOTICE OF AND CONTRIBUTED TO ILLEGAL DIVERSION OF PRESCRIPTION OPIOIDS

488. National retail pharmacy chains earned enormous profits by flooding the country with prescription opioids.[222] They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.

489. Each of the National Retail Pharmacies does substantial business throughout the United States. This business includes the distribution and dispensing of prescription opioids.

490. Statewide ARCOS data will confirm that the National Retail Pharmacies distributed and dispensed substantial quantities of prescription opioids, including fentanyl,

[222] Plaintiffs' allegations of wrongdoing are pointing to the National Retail Pharmacies not the pharmacy industry who in general serve a vital healthcare function in the US.

hydrocodone, and oxycodone in Florida. In addition, they distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to Florida. The National Retail Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it, and contributed substantially to the diversion problem.

491. The National Retail Pharmacies developed and maintained extensive data on opioids they distributed and dispensed. Through this data, National Retail Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and in Florida in particular. They used the data to evaluate their own sales activities and workforce. On information and belief, the National Retail Pharmacies also provided Defendants with data regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration. The National Retail Pharmacies' data is a valuable resource that they could have used to help stop diversion, but failed to do so.

A. The National Retail Pharmacies Have a Duty to Prevent Diversion

492. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

493. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." See 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who

fills the prescription." Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

494. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

495. Suspicious pharmacy orders include orders unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

496. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

497. Suspicious pharmacy orders are red flags for if not direct evidence of diversion.

498. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular

stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

499. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

500. Despite their legal obligations as registrants under the CSA, the National Retail Pharmacies allowed widespread diversion to occur—and they did so knowingly. They knew they made money by filling prescriptions, not by not filling prescriptions. They knew they made money by making it easy for doctors to refer patients to them to fill drug prescriptions, not by making it difficult for doctors to refer patients to them to fill prescriptions.

501. Performance metrics and prescription quotas adopted by the National Retail Pharmacies for their retail stores contributed to their failure. For instance, under CVS's Metrics System, for example, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply troubling and entirely predictable: opioids flowed out of National Retail Pharmacies and into communities throughout the country. The National Retail Pharmacies had no incentive to stop the outflow, and every financial incentive to further it. Their policies and practices remained in place even as the epidemic raged.

502. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that this problem was compounded by the National Retail Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes

a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

503. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that the National Retail Pharmacies also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

504. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that the National Retail Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

505. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that the National Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

506. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

507. The National Retail Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

B. Multiple Enforcement Actions against the National Retail Pharmacies Confirms Their Compliance Failures

508. The National Retail Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. In consideration of a reasonable opportunity for further investigation and discovery, Plaintiff alleges that based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the National Retail Pharmacies.

509. **CVS** is one of the largest companies in the world, with annual revenue of more than $150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations. CVS could be a force for good in connection with the opioid crisis, but like other Defendants, CVS sought profits over people.

510. CVS is a repeat offender; the company has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the DOJ. It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

511. As recently as July 2017, CVS entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances. [223]

512. This fine was preceded by numerous others throughout the county.

513. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.[224]

514. In October 2016, CVS paid $600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.[225]

---

[223] Press Release, U.S. Attorney's Office E. Dist. of Cal., *CVS Pharmacy Inc. Pays $5M to Settle Alleged Violations of the Controlled Substance Act*, U.S. Dep't of Just. (July 11, 2017), https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violationscontrolled-substance-act.

[224] Press Release, U.S. Attorney's Office Dist. of Md., *United States Reaches $8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances*, U.S. Dep't of Just. (Feb. 12, 2016), https://www.justice.gov/usao-md/pr/united-states-reaches-8-millionsettlement-agreement-cvs-unlawful-distribution-controlled.

[225] Press Release, U.S. Attorney's Office Dist. of Conn., *CVS Pharmacy Pays $600,000 to Settle Controlled Substances Act Allegations*, U.S. Dep't of Just. (Oct. 20, 2016), https://www.justice.gov/usao-ct/pr/cvs-pharmacy-pays-600000-settle-controlled-substances-actallegations.

515. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.[226]

516. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances— mostly addictive painkillers—more than 500 times between 2011 and 2014.[227]

517. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.[228]

---

[226] Dialynn Dwyer, *CVS will pay $795,000, strengthen policies around dispensing opioids in agreement with state*, Boston.com (Sept. 1, 2016), https://www.boston.com/news/localnews/2016/09/01/cvs-will-pay-795000-strengthen-policies-around-dispensing-opioids-inagreement-with-state.

[227] Press Release, U.S. Attorney's Office Dist. of Mass., *CVS to Pay $3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions*, U.S. Dep't of Just. (June 30, 2016), https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filledfake-prescriptions.

[228] Press Release, U.S. Attorney's Office Dist. of R.I., Drug Diversion Claims Against CVS Health Corp. Resolved With $450,000 Civil Settlement, U.S. Dep't of Just. (Aug. 10, 2015), https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement.

518. In May 2015, CVS agreed to pay a $22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."[229]

519. In September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.[230]

520. In August 2013, CVS was fined $350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.[231]

521. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.[232]

---

[229] Press Release, U.S. Attorney's Office M. Dist. of Fla., United States Reaches $22 Million Settlement Agreement With CVS For Unlawful Distribution of Controlled Substances, U.S. Dep't of Just. (May 13, 2015), https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution.

[230] Patrick Danner, H-E-B, CVS Fined Over Prescriptions, San Antonio Express-News (Sept. 5, 2014), http://www.expressnews.com/business/local/article/H-E-BCVSfined-over-prescriptions-5736554.php.

[231] Andrew Knittle, *Oklahoma pharmacy board stays busy, hands out massive fines at times*, NewsOK (May 3, 2015), http://newsok.com/article/5415840.

[232] Press Release, U.S. Attorney's Office W. Dist. of Okla., CVS to Pay $11 Million To Settle Civil Penalty Claims Involving Violations of Controlled Substances Act, U.S. Dep't of Just. (Apr. 3, 2013), https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penaltyclaims-involving-violations-controlled.

522. **Walgreens** is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

523. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales.[233] The allegations accused Walgreens of endangering public safety in that it allowed millions of controlled substances to reach the black market.

524. As part of the settlement, Walgreens admitted that it failed to uphold its obligations as a DEA registrant regarding the above-described conduct.[234]

525. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

526. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each

[233] Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of $80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-recordsettlement-80-million-civil-penalties-under-controlled.
[234] Id.

allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.[235]

527. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers not only turned a blind eye, but provided pharmacists with incentives through a bonus program that compensated them based on the number of prescriptions filled at the pharmacy. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities.[236]

528. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold

[235] Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).
[236] Id.

almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.[237]

529. The six retail pharmacies in Florida that received the suspicious drug shipments from the Jupiter Distribution Center, in turn, filled customer prescriptions that they knew or should have known were not for legitimate medical use.[412]

530. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).[413]

531. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

532. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.[238]

533. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from National Retail Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

533. The litany of state and federal actions against the National Retail Pharmacies demonstrate that they routinely, and as a matter of standard operation procedure, violated their

---

[237] *Walgreens to pay $200,000 settlement for lapses with opioids*, APhA (Jan. 25, 2017), https://www.pharmacist.com/article/walgreens-pay-200000-settlement-lapses-opioids.
[238] Id.

legal obligations under the CSA and other laws and regulations that govern the distribution and dispensing of prescription opioids.

534. Throughout the country and in Florida in particular, the National Retail Pharmacies were or should have been aware of numerous red flags of potential suspicious activity and diversion.

539. On information and belief, from the catbird seat of their retail pharmacy operations, the National Retail Pharmacies knew or reasonably should have known about the disproportionate flow of opioids into Florida and the operation of "pill mills" that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

540. On information and belief, the National Retail Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in the community.

541. On information and belief, because of (among others sources of information) regulatory and other actions taken against the National Retail Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the National Retail Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

542. The National Retail Pharmacies' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

VI. DEFENDANTS CAUSED HARM TO THE NAMED PLAINTIFF AND CLASS

543. Plaintiff and the putative class members he represents have treated, and continue to treat, numerous patients for opioid-related conditions, specifically, opioid overdose and misuse.

544. Opioid users present themselves to Plaintiff and the putative class claiming to have illnesses and medical problems, which are actually pretexts for obtaining opioids to satisfy their cravings. Plaintiff and the putative class members he represents, incur damages related to treatment of patients with OUD. These damages include non payment of services, underpayment of services, lost opportunity costs, and operational costs, fear of and reputational damage caused by poor patient satisfaction surveys, and expenses for mandated educational training in correct prescribing of opioids and otherwise dealing with these "pill seekers".

545. Plaintiff and the putative class, are required by law to treat emergency cases, including those as the result of opioid use and misuse. Regardless of whether a patient can pay, they must be provided medical care under prevailing federal and state law for medical and possible psychiatric care.

546. Plaintiff and the putative class, in essence, have been forced to provide an inordinate amount of emergency room services related to the “opioid epidemic,” either for no compensation or for compensation substantially below market rates due to the unlawful marketing, distribution and sale of opioids.

547. At times Plaintiff and the putative class were not compensated at all for services provided by uninsured patients. Medicaid payments were at below market rates.

548. In a 2021 survey of emergency physicians and professionals involved with billing for emergency department care, the most common response on the amount collected from uninsured patients for emergency physician professional services in 1,265 ED-Years for the period 2006-2021 was $21-$25. According to a May 2003 American Medical Association (AMA) study, emergency physicians annually incur, on average, $138,300 of EMTALA-related bad debt. Approximately 95.2% of emergency physicians provide some EMTALA mandated care in a typical week and more than one-third of emergency physicians provide more than 30 hours of EMTALA-related care each week and in many circumstances and, depending on the state in question, may not cover emergency physician costs for providing service.[239]

549. Average charges for opioid overdose patients treated and released from the emergency department are $3,397 per visit.[240]

550. In 2016, there were 42,249 opioid overdose deaths in the United States, more than quadruple the number in 2001.[241]

551. Research suggests that visits to emergency rooms for suspected opioid overdoses rose 30% in the United States from July 2016 to September 2017 across 45 states, and 35% across 16 states.[242]

---

[239] American College of Emergency Physicians , The Impact of Unreimbursed Care on the Emergency Physician,. https://www.acep.org/administration/reimbursement/the-impact-of-unreimbursed-care-on-the-emergency-physician/

[240] https://www.americanprogress.org/issues/healthcare/news/2017/06/20/434708/senates-opioid-fund-cannot-substitute-health-coverage/ (last accessed July 12, 2018)

[241] https://www.kff.org/medicaid/issue-brief/the-opioid-epidemic-and-medicaids-role-in-facilitating-access-to-treatment/) (last accessed July 12, 2018)

[242]https://www.pharmacytimes.com/news/cdc-emergency-department-data-signal-worsening-opioid-epidemic-, (accessed July 12, 2018)

552. The number of opioid misuse cases treated are commiserate with the number of opioid overdose.

553. These patients' opioid conditions are the direct and proximate result of the opioid epidemic created and engineered by Defendants.

554. Nationwide, 2.66 million people had OUD as of 2015. Of these, 1.37 million have incomes below 200 percent of the federal poverty level.[243]

555. The number of people treated for opioid use conditions who have incomes below 200 percent of the federal poverty level is 343,000 in 2015 and estimated to reach 1.1 million in 2026.[244]

556. Plaintiff and the Class members each have a price list, which sets the prices for a comprehensive listing of items billable to an emergency visit patient or the patient's health insurance provider.

557. These are the full charges for the independent emergency room physicians' services. The full charges are only partially reimbursed by private health insurers, Medicare, and Medicaid. Plaintiff and the Class members have provider agreements with private health insurers whereby they accept payment from the health insurers at a discounted rate on behalf of insured patients. The difference between the full charges and the discounted rate is lost to the Plaintiff and Class members. Medicare and Medicaid bill emergency room physicians at set rates that are less than the independent emergency room physicians' full charges, and the difference between the set rates and the full charges is lost to the independent emergency room physicians.

---

[243] https://www.americanprogress.org/issues/healthcare/news/2017/06/20/434708/senates-opioid-fund-cannot-substitute-health-coverage/ (accessed July 12, 2018)

[244] *Id.*

558. Plaintiff and the Class members bill their full charges to uninsured patients. Typically, where there is no health insurance, Medicare, or Medicaid coverage, these charges are not reimbursed and are lost to independent emergency room physicians.

559. Unlike Hospitals, Independent Emergency Room Physicians cannot seek additional payments from the Government for any underpayment resulting from providing treatment in a disproportionately lower reimbursement rate demographic/physical area.

560. Plaintiff and the Class members incur partial monetary losses for patients with health insurance, and total monetary losses for uninsured patients, in the treatment of patients with opioid conditions. These patients would not have presented to Plaintiff and the Class members, and would not have had opioid conditions, but for the opioid epidemic created and engineered by Defendants. Accordingly, Plaintiff's and the Class members' aforesaid monetary losses are the direct and proximate result of Defendants' acts and omissions previously specified herein.

561. By treating patients for opioid abuse and misuse issues, many of which were not insured or underinsured, Plaintiff and Class Members were unable to treat insured patients, incurring damages in lost opportunity costs.

562. Uninsured adults were more likely than those with private health insurance or a public health plan to visit the emergency room due to having no other place to go.[245]

563. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications[246]

564. Additionally, Because of the well-established relationship between the use of prescription opioids and the use of non-prescription opioids, like heroin, the massive distribution

---

[245] https://www.cdc.gov/nchs/data/nhis/earlyrelease/emergency_room_use_january-june_2011.pdf (accessed July 12, 2018).

[246] *See* Califf et al., supra n. 11.

of opioids by Defendants has caused the Defendant-caused opioid epidemic to include heroin addiction, abuse, and death.

565. Also during this time frame patient satisfaction surveys were implemented. Most Independent Emergency Room Physicians belong to groups. At times, the Physicians are the “member owners” of the Groups. The administrative duties of the Group are shared by the members, as well as the administrative expenses. Other models include “groups” that are separate entities that the physician is not an owner. The Independent Emergency Room Physician enters into an Independent Contractor arrangement with that group. Those contracts can be cancelled for performance issues. The patient satisfaction surveys were used by Hospitals and by the Groups that Plaintiff and the putative class contracted with, to rank the Plaintiff and the putative class and to use to claim poor performance. Those surveys were sent to the patient and the Plaintiff and putative class had no means by which to refute what was said. Additionally, no Group member reviewed the complaint and determined if it was valid or not. Poor satisfaction surveys were used to indicate a physician had performance issues and upon information and belief were used to cancel contracts.

566. Due to the opioid epidemic, Plaintiff and the Class of physicians are now mandated to attend continuing medical education courses on the appropriate use and prescribing of opioids. Plaintiff and the class incur actual unreimbursed expenses to attend these trainings and cannot schedule work shifts during the training time.

567. Defendants repeatedly and purposefully breached their duties under federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the

opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the United States. This diversion and the epidemic are direct causes of foreseeable harm to Plaintiff.

568. Defendants' marketing of opioids caused Plaintiff and the putative class he seeks to represent to diagnose, care for and treat opioid addicted patients who presented with opioid addicted symptoms, caused emotional distress and in some cases reputational loss due to patient satisfaction surveys and damages for mandatory training. All of these medical services provided by Plaintiff and other damages, were caused by Defendants' fraudulent marketing and scheme. Defendants should be held responsible for all economic damages suffered by Plaintiff and the putative class he seeks to represent. Plaintiff is obligated to cover medically necessary and reasonably required care; he had no choice but to provide these services although often he was not paid or was paid substantially less than market rates. Plaintiff was obligated to take additional training and also was subjected to patient satisfaction surveys that provided no due process procedures to refute.

569. The fact that Plaintiff and the class he seeks to represent would have to provide medical services for opioid addicted patients and incur other damage was both the foreseeable and intended consequence of Defendants' fraudulent marketing scheme. Defendants set out to change the medical and general consensus supporting chronic opioid therapy with the intention of encouraging doctors to prescribe, long- term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

570. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the opioid epidemic would result in a corresponding epidemic of patients with opioid conditions in emergency rooms. It was also foreseeable to Defendants that Plaintiff and the

Class members would suffer the aforesaid monetary losses because of the opioid epidemic, since independent emergency room physicians typically are not reimbursed for their treatment of uninsured patients and receive only partial reimbursement for their treatment of patients with health insurance and other training requirements would be mandated.

571. Defendants' misrepresentations were material to, and influenced, the opioid-addicted patients presented to Plaintiff and the class he seeks to represent. In the first instance, Plaintiff would not have been presented with, or required to diagnose, care and treat these opioid-addicted patients, but for Defendants' fraudulent and deceptive marketing. Second, Plaintiff has demonstrated that Defendants' marketing is material by setting forth in detail Defendants' wrongful acts.

572. Death statistics represent only the tip of the iceberg. According to 2009 data, for every overdose death that year, there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users. Nationally, there were more than 488,000 emergency room admissions for opioids other than heroin in 2008 (up from almost 173,000 in 2004).

573. Emergency room visits tied to opioid use likewise have sharply increased in throughout the country.

574. Emergency rooms are charged with great opportunity to address this opioid epidemic with proper support. Debra Houry, MD, MPH, Director of the National Center for Injury Prevention and Control at the CDC, emphasized that " EDs are a critical entry point for prevention of overdose , with opportunities to improve opioid prescribing, respond to overdoses with overdose education and naloxone distribution, engage in motivational interviewing of patients, initiate treatment for opioid use disorder, and improve surveillance efforts in collaboration with health

departments. EDs and physicians who engage in these efforts can save patient lives and reduce health care costs."[247]

VII. CONSPIRACY ALLEGATIONS

A. The Defendants Conspired To Engage In The Wrongful Conduct Complained Of Herein and Intended To Benefit Both Independently and Jointly From Their Conspiracy

575. **The Manufacturing Defendants** agreed among themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers, such as hospitals, and health care payors through misrepresentations and omissions regarding the appropriate uses, risks, and safety of opioids, to increase sales, revenue, and profit from their opioid products.

576. This interconnected and interrelated network relied on the Manufacturing Defendants' collective use of unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups developed and funded collectively by the Manufacturing Defendants and intended to mislead consumers and medical providers, such as hospitals, of the appropriate uses, risks, and safety of opioids.

577. The Manufacturing Defendants' collective marketing scheme to increase opioid prescriptions, sales, revenues and profits centered around the development, the dissemination, and reinforcement of nine false propositions: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition dubbed

[247] https://www.forbes.com/sites/robertglatter/2018/03/15/how-er-doctors-are-fighting-the-opioid-crisis/#5a0ef27554fd (accessed July 12, 2018).

"pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

578. The Manufacturing Defendants knew that none of these propositions is true and that there was no evidence to support them.

579. Each Manufacturing Defendant worked individually and collectively to develop and actively promulgate these nine false propositions in order to mislead physicians, patients, health care providers, such as hospitals and healthcare payors regarding the appropriate uses, risks, and safety of opioids.

580. What is particularly remarkable about the Manufacturing Defendants' effort is the seamless method in which the Manufacturing Defendants joined forces to achieve their collective goal: to persuade consumers and medical providers, such as hospitals of the safety of opioids, and to hide their actual risks and dangers. In doing so, the Manufacturing Defendants effectively built a new – and extremely lucrative – opioid marketplace for their select group of industry players.

581. The Manufacturing Defendants' unbranded promotion and marketing network was a wildly successful marketing tool that achieved marketing goals that would have been impossible to have been met by a single or even a handful of the network's distinct corporate members.

582. For example, the network members pooled their vast marketing funds and dedicated them to expansive and normally cost-prohibitive marketing ventures, such as the

creation of Front Groups. These collaborative networking tactics allowed each Manufacturing Defendant to diversify its marketing efforts, all the while sharing any risk and exposure, financial and/or legal, with other Manufacturing Defendants.

583. The most unnerving tactic utilized by the Manufacturing Defendants' network, was their unabashed mimicry of the scientific method of citing "references" in their materials. In the scientific community, cited materials and references are rigorously vetted by objective unbiased and disinterested experts in the field, and an unfounded theory or proposition would, or should, never gain traction.

584. Manufacturing Defendants put their own twist on the scientific method: they worked together to manufacture wide support for their unfounded theories and propositions involving opioids. Due to their sheer numbers and resources, the Manufacturing Defendants were able to create a false consensus through their materials and references.

585. An illustrative example of the Manufacturing Defendants' utilization of this tactic is the wide promulgation of the Porter & Jick Letter, which declared the incidence of addiction "rare" for patients treated with opioids. The authors had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. These patients were not given long-term opioid prescriptions or provided opioids to administer to themselves at home, nor was it known how frequently or infrequently and in what doses the patients were given their narcotics. Rather, it appears the patients were treated with opioids for short periods of time under in-hospital doctor supervision.

586. Nonetheless, Manufacturing Defendants widely and repeatedly cited this letter as proof of the low addiction risk in connection with taking opioids in connection with taking

opioids despite its obvious shortcomings. Manufacturing Defendants' egregious misrepresentations

based on this letter included claims that less than one percent of opioid users became addicted.

587. Manufacturing Defendants' collective misuse of the Porter & Jick Letter helped the opioid manufacturers convince patients and healthcare providers, such as hospitals that opioids were not a concern. The enormous impact of Marketing Defendants' misleading amplification of this letter was well documented in another letter published in the NEJM on June, 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases "grossly misrepresented." In particularly, the authors of this letter explained:

> [W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crises by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy...

By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, the Marketing Defendants committed overt acts in furtherance of their conspiracy.

2. Conspiracy Among All Defendants

588. In addition, and on an even broader level, all Defendants took advantage of the industry structure, including end-running its internal checks and balance, to their collective advantage. Defendants agreed among themselves to increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and supply of prescription opioids. Defendants did so to increase sales, revenue, and profit from their opioid products.

589. The interaction and length of the relationships between and among the Defendants reflects a deep level of interaction and cooperation between Defendants in a tightly knit industry.

The Marketing and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

590. Defendants collaborated to expand the opioid market in an interconnected and interrelated network in the following ways, as set forth more fully below including, for example, membership in the Healthcare Distribution Alliance.

591. Defendants utilized their membership in the HDA and other forms of collaboration to form agreements about their approach to their duties under the CSA to report suspicious orders. The Defendants overwhelmingly agreed on the same approach – to fail to identify, report or halt suspicious opioid orders, and fail to prevent diversion. Defendants' agreement to restrict reporting provided an added layer of insulation from DEA scrutiny for the entire industry as Defendants were thus collectively responsible for each other's compliance with their reporting obligations. Defendants were aware, both individually and collectively aware of the suspicious orders that flowed directly from Defendants' facilities.

592. Defendants knew that their own conduct could be reported by other Defendants and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting or suspicious orders to ensure consistency in their dealings with DEA.

593. The Defendants also worked together to ensure that the opioid quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

594. The desired consistency, and collective end goal was achieved. Defendants achieved blockbuster profits through higher opioid sales by orchestrating the unimpeded flow of opioids.

B. Statutes Of Limitations Are Tolled and Defendants Are Estopped From Asserting Statutes Of Limitations As Defenses

1. Continuing Conduct

595. Plaintiff contends it continues to suffer harm from the unlawful actions by the Defendants.

596. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated. The conduct causing the damages remains unabated.

2. Equitable Estoppel and Fraudulent Concealment

597. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive Plaintiff and to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff, and Plaintiff's Community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits.

598. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the State, the Plaintiff, and Plaintiff's Community, that they are working to curb the opioid epidemic.

599. The Defendants were deliberate in taking steps to conceal their conspiratorial behavior and active role in the deceptive marketing and the oversupply of opioids through overprescribing and suspicious sales, all of which fueled the opioid epidemic.

600. As set forth herein, the Marketing Defendants deliberately worked through Front Groups purporting to be patient advocacy and professional organizations, through public relations companies hired to work with the Front Groups and through paid KOLs to secretly control messaging, influence prescribing practices and drive sales. The Marketing Defendants concealed their role in shaping, editing, and approving the content of prescribing guidelines, informational brochures, KOL presentations and other false and misleading materials addressing pain management and opioids that were widely disseminated to regulators, prescribers and the public at large. They concealed the addictive nature and dangers associated with opioid use and denied blame for the epidemic attributing it instead solely to abuse and inappropriate prescribing. They manipulated scientific literature and promotional materials to make it appear that misleading statements about the risks, safety and superiority of opioids were actually accurate, truthful, and supported by substantial scientific evidence. Through their public statements, omissions, marketing, and advertising, the Marketing Defendants' deceptions deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

601. The Supply Chain and Marketing Defendants also concealed from Plaintiff the existence of Plaintiff's claims by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law

enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and the public, including Plaintiff, and deprived Plaintiff of actual or implied knowledge of facts sufficient to put Plaintiff on notice of potential claims.

602. Plaintiff did not discover the nature, scope and magnitude of Defendants' misconduct, and its full impact on jurisdiction, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

603. The Marketing Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Plaintiff's Community deceived the medical community, consumers, the State, and Plaintiff's Community.

604. Further, Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, which will confirm their identities and the extent of their wrongful and illegal activities. On April 11, 2018, the Northern District of Ohio Ordered the transactional ARCOS data be produced, over Defendants' strenuous objections. In so doing, the Court reviewed its previous decisions on this data and held that, because the transaction data had not yet been produced, the Plaintiff could not identify the potential defendants in this litigation, and further held that such information was "critical":

> This means Plaintiffs still do not know: (a) which manufacturers (b) sold what types of pills (c) to which distributors; nor do they know (d) which distributors (e) sold what types of pills (f) to which retailers (g) in what locations. In any given case, therefore, the Plaintiff still cannot know for sure who are the correct defendants, or the scope of their potential liability. For example, the ARCOS spreadsheets produced by DEA show the top five distributors of oxycodone in Ohio in 2014 were Cardinal, AmerisourceBergen, McKesson, Wal-Mart, and Miami-Luken; but there is no way to

> know whether (or how much) any of these five entities distributed oxycodone into Seneca County, Ohio (or any other particular venue). . . . [The] DEA and [the] defendants . . . [have] conceded the data was relevant and necessary to litigation . . . . Discovery of precisely which manufacturers sent which drugs to which distributors, and which distributors sent which drugs to which pharmacies and doctors, is critical not only to all of plaintiffs' claims, but also to the Court's understanding of the width and depth of this litigation.

Order of April 11, 2018 [Doc. 233] at pp. 6-7 (footnotes omitted).

605. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff, other medical providers and the public. These entities and individuals did not know and did not have the means to know the truth, due to Defendants' actions and omissions.

606. The Plaintiff and others reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

C. Facts Pertaining to Punitive Damages

607. As set forth above, Defendants acted deliberately to increase sales of, and profits from, opioid drugs. The Marketing Defendants knew there was no support for their claims that addiction was rare, that addiction risk could be effectively managed, that signs of addiction were merely "pseudoaddiction," that withdrawal is easily managed, that higher doses pose no significant additional risks, that long-term use of opioids improves function, or that time-release or abuse-deterrent formulations would prevent addiction or abuse. Nonetheless, they knowingly promoted these falsehoods in order to increase the market for their addictive drugs.

608. All of the Defendants, moreover, knew that large and suspicious quantities of opioids were being poured into communities throughout the United States, yet, despite this knowledge, took no steps to report suspicious orders, control the supply of opioids, or otherwise prevent diversion. Indeed as described above, Defendants acted in concert together to maintain

high levels of quotas for their products and to ensure that suspicious orders would not be reported to regulators.

609. Defendants' conduct was so willful and deliberate that it continued in the face of numerous enforcement actions, fines, and other warnings from state and local governments and regulatory agencies. Defendants paid their fines, made promises to do better, and continued on with their marketing and supply schemes. This ongoing course of conduct knowingly, deliberately and repeatedly threatened and accomplished harm and risk of harm to public health and safety, and large scale economic loss to communities and government liabilities across the country.

The Marketing Defendants Persisted in Their Fraudulent Scheme Despite Repeated Admonitions, Warnings, and Even Prosecutions

610. So determined were the Marketing Defendants to sell more opioids that they simply ignored multiple admonitions, warnings and prosecutions, as described more fully below.

a. FDA Warnings To Janssen Failed To Deter Janssen's Misleading Promotion Of Duragesic

611. On February 15, 2000, the FDA sent Janssen a letter concerning the dissemination of "homemade" promotional pieces that promoted the Janssen drug Duragesic in violation of the Federal Food, Drug, and Cosmetic Act. In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance." The March 30, 2000 letter detailed numerous ways in which Janssen's marketing was misleading.

612. The letter did not stop Janssen. On September 2, 2004, the U.S. Department of Health and Human Services ("HHS") sent Janssen a warning letter concerning Duragesic due to

"false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products." The September 2, 2004 letter detailed a series of unsubstantiated, false or misleading claims.

613. One year later, Janssen was still at it. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been "'examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch'" and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic approved only for chronic pain in opioid-tolerant patients that could not be treated by other drugs.

614. In 2001, Janseen was advised by its own hired scientific advisory board many of the primary marketing messages Defendants used to promote opioids in general , and Duragesic specifically, were misleading and should not be disseminated, and there was no data to support the message this had low abuse protentional.

b. Governmental Action, Including Large Monetary Fines, Failed To Stop Cephalon From Falsely Marketing Actiq For Off-Label Uses

615. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon had trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare

professionals to speak to physicians about off-label uses of the three drugs and funded CME to promote off-label uses.

616. Notwithstanding letters, an FDA safety alert, DOJ and state investigations, and the massive settlement, Cephalon has continued its deceptive marketing strategy.

c. FDA Warnings Did Not Prevent Cephalon from Continuing False and Off-Label Marketing of Fentora

617. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: “Fentora should not be used to treat any type of short-term pain.” Indeed, FDA specifically denied Cephalon’s application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

618. Flagrantly disregarding the FDA’s refusal to broaden the indication for Fentora, Cephalon nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora (“Warning Letter”). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden “the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case.” It further criticized Cephalon’s other direct Fentora advertisements because they did not disclose the risks associated with the drug.

619. Despite this warning, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq. For example, on January 13, 2012, Cephalon published an insert in

Pharmacy Times titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."

d. A Guilty Plea and a Large Fine Did Not Deter Purdue from Continuing Its Fraudulent Marketing of OxyContin

620. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science. Additionally, Michael Friedman the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell, Purdue's top lawyer, also pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty as well and agreed to pay $7.5 million in fines.

621. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and fund seemingly neutral organizations to disseminate the message that opioids were non-addictive as well as other misrepresentations. At least until early 2018, Purdue continued deceptively to market the benefits of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007, it assembled an army of lobbyists to fight

any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly $900 million dollars on lobbying and political contributions - eight times what the gun lobby spent during that period.

e. Repeated Admonishments and Fines Did Not Stop Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion

622. Defendants were repeatedly admonished and even fined by regulatory authorities, but continued to disregard their obligations to control the supply chain of dangerous opioids and to institute controls to prevent diversion.

623. In a *60 Minutes* interview last fall, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die." He further explained that:

> JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.

624. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing." He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."[428]

625. Government actions against the Defendants with respect to their obligations to control the supply chain and prevent diversion include:

a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an Order to Show Cause against the Cardinal Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. In September 30, 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

g. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and

h. On December 23, 2016, Cardinal agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.

626. McKesson's deliberate disregard of its obligations was especially flagrant. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 McKesson MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program."

627. Despite its 2008 agreement with DEA, McKesson continued to fail to report suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring program it agreed to. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers and bypassed suspicious order reporting procedures set forth in the CSMP.

628. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland, FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Sante Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA. McKesson's 2017 agreement with DEA documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."

629. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty than the $150 million ultimately agreed to for McKesson's continued and renewed breach of its duties, as much as a billion dollars, and delicensing of certain facilities. A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."

630. On December 17, 2017, CBS aired an episode of 60 Minutes featuring Assistant Special Agent Schiller, who described McKesson as a company that killed people for its own financial gain and blatantly ignored the CSA requirement to report suspicious orders:

> DAVID SCHILLER: If they would stayed in compliance with their authority and held those that they're supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near.
>
> * * *
>
> They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.
>
> [INTERVIEWER:] And they had none.
>
> DAVID SCHILLER: They weren't reporting any. I mean, you have to understand that, nothing was suspicious?[248]

[248] Whitaker, Opioid Crisis Fueled by Drug

631 . Following the 2017 settlement, McKesson shareholders made a books and records request of the company. According to a separate action pending on their behalf, the Company's records show that the Company's Audit Committee failed to monitor McKesson's information reporting system to assess the state of the Company's compliance with the CSA and McKesson's 2008 Settlements. More particularly, the shareholder action alleges that the records show that in October 2008, the Audit Committee had an initial discussion of the 2008 Settlements and results of internal auditing, which revealed glaring omissions; specifically:

a. some customers had "not yet been assigned thresholds in the system to flag large shipments of controlled substances for review";

b. "[d]ocumentation evidencing new customer due diligence was incomplete";

c. "documentation supporting the company's decision to change thresholds for existing customers was also incomplete"; and

d. Internal Audit "identified opportunities to enhance the Standard Operating Procedures."

632 Yet, instead of correcting these deficiencies, after that time, for a period of more than four years, the Audit Committee failed to address the CSMP or perform any more audits of McKesson's compliance with the CSA or the 2008 Settlements, the shareholder action's description of McKesson's internal documents reveals. During that period of time,

633 McKesson's Audit Committee failed to inquire whether the Company was in compliance with obligations set forth in those agreements and with the controlled substances regulations more Industry generally. It was only in January 2013 that the Audit Committee received an Internal Audit report touching on these issues.

634 In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted. Quite the opposite, "their bad

acts continued and escalated to a level of egregiousness not seen before." According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in the Washington Post, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings." "Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."

635. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Purdue claims that health care providers added to the database no longer were detailed, and that sales representatives received no compensation tied to these providers' prescriptions.

636. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. Purdue's former senior compliance officer acknowledged in an interview with the Los Angeles Times that in five years of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

637. The same was true of prescribers. For example, as discussed above, despite Purdue's knowledge of illicit prescribing from one Los Angeles clinic which its district manager

called an "organized drug ring" in 2009, Purdue did not report its suspicions until long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

638. Indeed, the New York Attorney General found that Purdue placed 103 New York health care providers on its "No-Call" List between January 1, 2008 and March 7, 2015, and that Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period.

639. As all of the governmental actions against the Marketing Defendants and against all the Defendants shows, Defendants knew that their actions were unlawful, and yet deliberately refused to change their practices because compliance with their legal obligations would have decreased their sales and their profits.

640. The opiod epidemic remains an immediate hazard to public health and safety

641. The Distributor Defendants intentionally continued their conduct as alleged herein, with knowledge such conduct was creating the opioid crisis and causing the harms and damages alleged herein.

VIII. RICO ALLEGATIONS

A. The Opioid Diversion Enterprise

642. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress

enacted the Controlled Substances Act in 1970.[249] The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals.[250] Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.[251] As reflected in comments from United States Senators during deliberation on the CSA, the "[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls."[252] Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the "widespread diversion of [controlled substances lout of legitimate channels into the illegal market."[253] Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.[254] All registrants -- manufacturers and distributors alike -- must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.[255] When registrants at any level

[249] Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney Genera*l, D.D.C. Case No. 12- cv-185 (Document 14-2 February 10, 2012).
[250] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.
[251] *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20; 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).
[252] *See* H.R Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Congo Rec. 977-78 (Comments of Sen. Dodd, Jan 23, 1970).
[253] *See* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).
[254] *See* Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (available at https://www.dea.gov/pr/speeches-testimony/2012-2009/responding-to-prescription-drug-abuse.PDF).
[255] *Id*.

fail to fulfill their obligations, the necessary checks and balances collapse.[256] The result is the scourge of addiction that has occurred.

643. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, design and operate a system to disclose suspicious orders, and to inform the DEA of any suspicious orders.[257] The DEA also published suggested questions that a distributor should ask prior to shipping controlled substances, in order to "know their customers."[258]

644. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs."[259] When evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the Department of Health and Human Services;

b. Total net disposal of the basic class by all manufacturers;

---

[256] Joseph T. Rannazzisi Decl. ¶10, *Cardinal Health, Inc. V. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 2012).
[257] Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (September 27.2006); Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (December 27, 2007).
[258] Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf) (accessed July 13, 2018).
[259] 1970 U.S.C.C.A.N. 4566 at 5490; see also Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf) (accessed July 13, 2018).

c. Trends in the national rate of disposal of the basic class;

d. An applicant's production cycle and current inventory position;

e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and

f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.[260]

645. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.[261]

646. At all relevant times, the RICO Defendants[262] operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

---

[260] *See* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf) (accessed July 13, 2018).
[261] *Id*. (*citing* 21 U.S.C. 842)).
[262] The term "RICO Defendants" shall hereinafter refer to all Defendants, ~~.~~

647. The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, per capita purchase of methadone, hydrocodone, and oxycodone increased 13-fold, 4- fold, and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the county with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[263] On information and belief, the Opioid Diversion Enterprise has been ongoing for at least the last decade.[264]

648. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. It Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. But, it was not until recently that United States and State regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public.

649. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Defendants; (d) characterized by interpersonal relationships among the RICO Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. *Turkette,* 452 U.S. at 580; *Boyle,* 556 U.S. at 944 (2009). Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result

[263] Keyes KM, Cerda M, Brady JE, Havens JR, Galea S. Understanding the rural-urban differences in nonmedical prescription opioid use and abuse in the United States. Am J Public Health. 2014;104(2):eS2-9.

[264] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2016, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic (last accessed Jul. 12, 2018).

of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the RICO Defendants would have a larger pool of prescription opioids from which to profit.

650. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the RICO Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum (described in greater detail below) and the Healthcare Distribution Alliance lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations[265] The HDA and other members of the Pain Care Forum contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. Plaintiff is informed and believe that the Pain Care Forum and their members poured at least $3.5 million into lobbying efforts in this jurisdiction while the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

[265] *See* HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.8f84381a0ebe, (accessed July 13, 2018); Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.61f36a18c2c9, (accessed July 13, 2018); Eric Eyre, DEA Agent:"We Had no Leadership" in WV Amid Flood of Pain Pills,Charleston Gazette-Mail, Feb. 18, 2017, https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html, (accessed July 13, 2018).

651. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the RICO Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

652. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the County and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

653. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the RICO Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

654. Each of the RICO Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The RICO Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the RICO Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

655. The RICO Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum, the HDA, and through their contractual relationships.

656. The Pain Care Forum ("PCF") has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

657. The Center for Public Integrity and The Associated Press obtained "internal documents shed [ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[266] Specifically, PCF members spent over $740

[266] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017,12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic (emphasis added), (accessed July 13, 2018).

million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[267]

658. Not surprisingly, each of the RICO Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.[268] In 2012, membership and participating organizations included the HDA (of which all RICO Defendants are members), Non- Defendant Purdue, Johnson & Johnson (the parent company for Janssen Pharmaceuticals), Actavis *(i.e.,* Allergan), and Teva (the parent company of Cephalon).[269] Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.[270] Plaintiff is informed and believe that the Distributor Defendants participated directly in the PCF as well.

659. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing on the subject of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person" at the monthly meetings.

---

[267] *Id*.
[268] PAIN CARE FORUM 2012 Meetings Schedule, (last updated April 2012), http://www.documentcloud.org/documents/3108983-PAIN-CARE-FORUM-Meetings-Schedule-amp.html, (accessed July 13, 2018)
[269] *Id*. Plaintiff is informed and believes that Mallinckrodt became an active member of the PCF sometime after 2012.
[270] *Id*. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Phannaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Phannaceutical for McKesson Corporation. Executive Committee, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/executive-committee (accessed on July 12, 2018).

And, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."

660. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drug makers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

661. Second, the HDA -- or Healthcare Distribution Alliance -- led to the formation of interpersonal relationships and an organization between the RICO Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis *(i.e.,* Allergan), and Cephalon were members of the HDA.[271] And, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

662. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and

[271] Manufacturer Membership, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/membership/manufacturer (accessed on July 12, 2018).

working groups with peers and trading partners," and "make connections."[272] Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

663. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the RICO Defendants.[273] The manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.[274]

664. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."[275]

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major

---

[272] Manufacturer Membership Benefits, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en (accessed on July 12, 2018).
[273] *Id*.
[274] *Id*.
[275] Councils and Committees, Hea1thcare Distribution Alliance, https://www.healthcaredistribution.org/about/councils-and-committees (accessed on July 12,2018)

areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of ecommerce." Participation in this committee includes distributors and manufacturer members.[276]

c. Health, Beauty and Wellness Committee: "This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain." Participation in this committee includes distributors and manufacturer members.[277]

d. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.[278]

e. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such

[276] *Id*.
[277] *Id*.
[278] *Id*.

issues as prescription drug traceability, distributor licensing, and FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation ill this committee includes manufacturer members.[279]

f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[280]

g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.[281]

h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.[282]

665. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation includes Distributor and Manufacturer Members.[283]

666. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization.

667. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA, and the Distributor Defendants advertise these conferences to the Manufacturer Defendants The conferences also gave the Manufacturer and Distributor

[279] *Id.*
[280] *Id.*
[281] *Id*
[282] *Id.*
[283] *Id.*

Defendants "unmatched opportunities to network with their 1 peers and trading partners at all levels of the healthcare distribution industry."[284] The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. Upon information and belief, Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.

668. Third, the RICO Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

669. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids.[285] As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.[286] On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription

---

[284] *Id.*
[285] Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.ed5a9c8f3a6f, (accessed July 13, 2018); *see also*, Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letters From Sen. Claire McCaskill, (March 28, 2017), https://www.hsgac.senate.gov/imo/media/doc/McCaskill%20Opioid%20Letters.pdf; Purdue Managed Markets, Purdue Pharma, (accessed on July 12, 2018),http://www.purduepharma.com/payers/managed-markets/.
[286] *Id.*

opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.[287] The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to cost effectively sell the prescription opioids.

670. The contractual relationships among the RICO Defendants also include vault security programs. The RICO Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Plaintiff is informed and believes that manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. Plaintiff is informed and believes that these agreements were used by the RICO Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

671. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the RICO Defendants was in communication and cooperation.

[287] Webinars, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/resources/webinar-leveraging-edi (accessed on July 12, 2018).

672. According to articles published by the Center for Public Integrity and The Associated Press, the Pain Care Forum -- whose members include the Manufacturers and the Distributors' trade association has been lobbying on behalf of the Manufacturers and Distributors for "more than a decade."[288] And, from 2006 to 2016 the Distributors and Manufacturers worked together through the Pain Care Forum to spend over $740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures.[289] Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.[290]

673. As described above, the RICO Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to promote the common purpose of their enterprise. Plaintiff is informed and believes that the RICO Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

B. Conduct of the Opioid Diversion Enterprise

674. During the time period alleged in this Complaint, the RICO Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into

[288] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic, (accessed on July 12, 2018).
[289] *Id*.
[290] HDA History, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/hda-history (accessed on July 12, 2018).

the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits, as follows:

a. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

b. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

c. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

d. Defendants paid nearly $800 million dollars to influence local, state and federal governments through joint lobbying efforts as part of the Pain Care Forum. The RICO Defendants were all members of their Pain Care Forum either directly or indirectly through the HDA. The lobbying efforts of the Pain Care Forum and its members, included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

675. The RICO Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

676. The RICO Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[291]

677. The RICO Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Plaintiff is informed and believes that the Manufacturer Defendants used the chargeback program to acquire detailed high-level data regarding sales of the opioids they manufactured. And, Plaintiff is informed and believes that the Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

678. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the RICO Defendants.

---

[291] *See* HDMA is now the Healthcare Distribution Alliance, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance; Lenny Bernstein & Scott Higham, Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html?utm_term=.8f84381a0ebe (accessed July 16, 2018); Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html?utm_term=.61f36a18c2c9 (accessed July 16, 2018); Eric Eyre, DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-/eadership-in-wv-amid-flood-of-pain-pills-. (last accessed Jul. 12, 2018)

679. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the RICO Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[292] On information and belief, the "know your customer" questionnaires informed the RICO Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

680. The RICO Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The RICO Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[293] and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders -- all for failure to report suspicious orders.[294]

---

[292]Suggested Questions a Distributor should ask prior to shipping controlled substances, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. Pharmaceutical Production Diversion: Beyond the PDMA, Purdue Pharma and McQuite Woods LLC, (available at https://www.mcguirewoods.com/newsresources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

[293] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, The Drug Enforcement Administration's Adjudication of Registrant Actions 6 (2014), https://oig.justice.gov/reportsl2014/e1403.pdf.

[294] *Id.*

681. Defendants' scheme had decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the State and Federal Government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and identify suspicious orders and report them to the DEA.

682. The RICO Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro-opioid. The Manufacturer and Distributor Defendants did this through their participation in the Pain Care Forum and Healthcare Distributors Alliance.

683. The RICO Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the RICO Defendants ensured that the DEA had no basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders. The RICO Defendants influenced the DEA production quotas in the following ways:

a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;

b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;

c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;

d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing opioids."[295]

f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

h. The RICO Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

i. The RICO Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and

[295] Harriet Ryan, et al., More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew, Los Angeles Times, (July 10,2016), http://www.latimes.com/projects/la-me-oxycontin-part2/ (accessed July 12, 2018)

j. The RICO Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA.

684. The scheme devised and implemented by the RICO Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

C. Pattern Of Racketeering Activity

685. The Rico Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 18 § 1961(D) by the felonious manufacture, importation, receiving, concealment buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

1. The RICO Defendants Engaged in Mail and Wire Fraud

686. The RICO Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

687. The RICO Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The RICO Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

688. The RICO Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

689. In devising and executing the illegal scheme, the RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

690. The RICO Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, and misrepresentations, promises, and omissions.

691. The RICO Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of the RICO Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;

c. Defendants' DEA registrations;

d. Documents and communications that supported and/or facilitated Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Manufacturers;

k. Rebates and chargebacks from the Manufacturers to the Distributors;

l. Payments to Defendants' lobbyists through the Pain Care Forum;

m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

692. On information and belief, the RICO Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

693. <u>Non Defendant Purdue manufactures multiple forms of prescription opioids, including but not limited to: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla</u>

ER, and Targiniq ER. Purdue manufactured and shipped these prescription opioids to the Distributor Defendants.

694. The Distributor Defendants shipped Purdue's prescription opioids throughout the United States.

695. Cephalon manufactures multiple forms of prescription opioids, including but not limited to: Actiq and Fentora. Cephalon manufactured and shipped these prescription opioids to the Distributor Defendants.

696. The Distributor Defendants shipped Teva' s prescription opioids throughout the United States.

697. Janssen manufactures prescription opioids known as Duragesic. Janssen manufactured and shipped its prescription opioids to the Distributor Defendants.

698. The Distributor Defendants shipped Janssen's prescription opioids throughout the United States.

699. The Distributor Defendants shipped Janssen's prescription opioids throughout the United States.

700. Actavis manufactures multiple forms of prescription opioids, including but not limited to: Kadin and Norco, as well as generic versions of the drugs known as Kadian, Duragesic and Opana. Actavis manufactured and shipped its prescription opioids to the Distributor Defendants.

701. The Distributor Defendants shipped Actavis' prescription opioids throughout the United States.

702. Mallinckrodt manufactures multiple forms of prescription opioids, including but not limited to Exalgo and Roxicodone.

703. The Distributor Defendants shipped Mallinckrodt's prescription opioids throughout the United States.

704. The RICO Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

705. At the same time, the RICO Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

706. Plaintiff is also informed and believes that the RICO Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

707. The RICO Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

708. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Defendants' scheme

and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

709. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. But, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

710. The RICO Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and/or minimize the losses for the RICO Defendants.

711. The RICO Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

712. The RICO Defendants hid from the general public, and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the RICO Defendants were filling on a daily basis – leading to the diversion of a tens of millions of doses of prescription opioids into the illicit market.

713. The RICO Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

714. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

715. As described herein, the RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

716. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Defendants while Plaintiff was left with substantial monetary losses through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the RICO Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

717. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

718. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future.

719. Many of the precise dates of the RICO Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioids Addiction and Opioid Diversion Enterprise alleged herein depended upon secrecy.

720. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including the Plaintiff and the proposed Class members. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to effects such as behavior would have on consumers, Plaintiff, or the proposed Class members. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products.

721. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct consulting a pattern of racketeering activity.

722. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulation, would harm Plaintiff as set out herein, by allowing the flow of prescription opioids from appropriate medical channels into illicit drug market.

723. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

D. The RICO Defendants Manufactured, Sold and/or Dealt in Controlled Substances and Their Crimes Are Punishable as Felonies

724. The RICO Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defines in 18 U.S.C.

§ 1961 (D) by the felonious manufacturer, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

725. The RICO Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

726. Each of the RICO Defendants qualify as registrants under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances. and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

727. Pursuant to the CSA and the Code of Federal Regulations, the RICO Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

728. The RICO Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the RICO Defendants were aware of suspicious orders of prescription opioids and the diversion of their

prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

729. For example, The DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay $150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.[296]

730. Plaintiff is informed and believes that the foregoing example reflect the RICO Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants.[297] For example:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

[296] McKesson, McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims, About McKesson I Newsroom I Press Releases, (January 17, 2017), http://www.mckesson.com/about-mckesson/newsroom/press-releasea/2017/mckesson-finalizes-settlement-with-doj-and-dea-to-resolve-past-claims/ (last accessed July 12, 2018).

[297] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, The Drug Enforcement Administration's Adjudication of Registrant Actions 6 (2014),https://oig.justice.gov/reports/2014/e1403.pdf.

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

j. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

731. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

732. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future.

733. Many of the precise dates of Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

734. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers and Plaintiff and the proposed Class members. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on consumers, Plaintiff, and the proposed Class members.

735. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

736. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiff as set out herein by

allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

737. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

VIII. CLASS ALLEGATIONS

738. This action is brought as a plaintiff's class action pursuant to Federal Rule of Civil Procedure 23(b)(3). Plaintiff brings this action on their own behalf, and on behalf of all others similarly situated, as representatives of the following Class:

> All independent emergency room physicians in the United States which treated patients with opioid conditions within the applicable statute of limitations.
>
> Excluded from the Class are any emergency room physicians directly or indirectly owned or operated by Defendants or Defendants' affiliated entities or that are W-2 employees of Hospitals.

739. The members of the Class are readily identifiable from public records.

740. Upon information and belief, the Class consists of thousands of members, and is therefore so numerous that individual joinder of all members is impracticable. The members of the Class are geographically dispersed throughout the United States.

741. There are questions of law and fact common to the Class, which predominate over any questions affecting only individual members of the Class. The wrongs suffered and remedies sought by Plaintiff and the other members of the Class are premised upon a uniform unlawful scheme perpetuated by Defendants. The sole question affecting only individual members of the

Class is the exact monetary recovery to which each Class member is entitled. Questions common to the Class include, but are not limited to, the following:

a. Did the Manufacturer Defendants use false and deceptive statements and omissions to market opioids?

b. Did the Manufacturer Defendants market opioids by misrepresenting the risks and benefits of opioids?

c. Did the Manufacturer Defendants and the Distributor Defendants fail to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids?

d. Did the Manufacturer Defendants and the Distributor Defendants fail to monitor, detect, investigate, refuse to fill, and report orders of prescription opioids which they knew or should have known were likely to be diverted for nonmedical purposes?

e. Did the Defendants conduct the affairs of an enterprise through a pattern of racketeering activity?

f. Did the Defendants conspire to conduct the affairs of an enterprise through a pattern of racketeering activity?

g. Did the Manufacturer Defendants negligently manufacture, market, and sell opioids?

h. Did the Distributor Defendants negligently sell and distribute opioids?

i. Did the Manufacturer Defendants wantonly, recklessly, or with gross negligence manufacture, market, and sell opioids?

j. Did the Distributor Defendants wantonly, recklessly, or with gross negligence sell and distribute opioids?

k. Did the Defendants committee common-law fraud by making false representations of material fact and by concealing material facts about opioids?

l. Were Plaintiff and the Class members monetarily damaged as a direct and proximate result of the Defendants' acts and omissions?

742. Plaintiff's claims are typical of those of the Class, and are based on the same legal theories as those of the Class members. Plaintiff's claims and those of the Class members all arise from the same pattern or practice by the Defendants, set out above.

743. Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff has retained counsel who is highly experienced and competent in complex consumer class-action litigation, and Plaintiff and their counsel intend to prosecute this action vigorously. Neither Plaintiff nor their counsel has any interests that might cause them not to vigorously pursue this action. Plaintiff's interests are coextensive with those of the Class, and Plaintiff has no interests adverse to those of the Class members.

744. Plaintiff has made arrangements with their counsel for the discharge of their financial responsibilities to the Class. Plaintiff's counsel has the necessary financial resources to adequately and vigorously litigate this class action.

745. A class action is superior to all other available means for the fair and efficient adjudication of this controversy. It is desirable to concentrate the litigation of the claims in this forum, because the damages suffered by the individual Class members are relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Defendants. Moreover, the individual Class members are unlikely to be aware of their rights. Thus, it is unlikely that the Class members, on an individual basis, can obtain effective redress for the wrongs done to them. Additionally, the court system would be adversely

affected by such individualized litigation. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase delay and expense to all parties and the court system from the issues raised by this action. In contrast, the class-action device provides the benefit of adjudication of these issues in a single proceeding, with economies of scale and comprehensive supervision by a single court.

746. Plaintiff and their counsel are aware of no litigation concerning the controversy already begun by or against Class members. This also indicates that the Class members' interest in individually controlling the prosecution of separate actions is minimal.

CAUSES OF ACTION

COUNT I: RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT 18 U.S.C. 1961 , ET SEQ.

747. Plaintiff, individually and on behalf of the putative Class, realleges and incorporates by reference paragraphs 1-748 as if stated fully herein.

748. Plaintiff brings this Count against the following Defendants, as defined above: Cephalon, Janssen, Actavis, McKesson, Cardinal, and AmerisourceBergen (collectively, for purposes of this Count, the "RICO Defendants").

749. The RICO Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the RICO Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

750. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference Paragraphs 324 through 355 concerning the Opioid Diversion Enterprise.

751. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference Paragraphs 356 through 366 concerning the Conduct of the Opioid Diversion Enterprise.

752. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference Paragraphs 367 through 422 concerning the Pattern of Racketeering Activity of the Opioid Diversion Enterprise.

753. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); *United State v. Turkette*, 452 U.S. 576, 580 (1981).

754. The term "enterprise" is defined as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4); Turkette, 452 U.S. at 580; Boyle v. U.S., 556 U.S. 938, 944 (2009). The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section "describes two separate categories of associations that come within the purview of an 'enterprise' -- the first encompassing organizations such as corporations, partnerships, and other 'legal entities,' and the second covering 'any union or group of individuals associated in fact although not a legal entity. '" *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. Id.

755. For over a decade, the RICO Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the RICO Defendants operated and continue to operate within the "closed-system" created under the Controlled Substances Act, 21 U.S.C. § 821, et seq. (the "CSA"). The CSA restricts the RICO Defendants' ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

756. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from "legitimate channels of trade" to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances]."

757. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined above) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. As discussed in detail below, through the RICO Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly

engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA. In doing so, the RICO Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate obscene profits.

758. Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed in perfect harmony by each of them. In particular, each of the RICO Defendants were associated with, and conducted or participated in, the affairs of the RICO enterprise (defined below and referred to collectively as the "Opioid Diversion Enterprise"), whose purpose was to engage in the unlawful sales of opioids, and deceive the public and federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations. The RICO Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the RICO Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like Plaintiff experienced tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the RICO Defendants' misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

759. Alternatively, the RICO Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically,

the Healthcare Distribution Alliance (the "HDA") is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because It is a corporation and a legal entity.

760. On information and belief, each of the RICO Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

761. Each of the RICO Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and Manufacturers beyond the RICO Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the RICO Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

762. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association in- fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion Enterprise. "The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff and the proposed Class members injury in their businesses, as described above in language expressly incorporated herein by reference.

763. Plaintiff's and the proposed Class members' injuries were proximately caused by Defendants' racketeering activities. But for the RICO Defendants' conduct, Plaintiff and the

proposed Class members would not have incurred the losses described above and expressly incorporated herein by reference.

764. Plaintiff's and the proposed Class members' injuries were directly caused by the RICO Defendants' racketeering activities.

765. Plaintiff seeks actual damages, treble damages, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT II: RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT 18 U.S.C. 1962(d), *et seq.*

(Against all Defendants)

766. Plaintiff, individually and on behalf of the putative Class, realleges and incorporates by reference paragraphs 1-748 as if stated fully herein.

767. Plaintiff brings this Count against the following Defendants, as defined above: Cephalon, Janssen, Actavis, McKesson, Cardinal, and AmerisourceBergen (collectively, for purposes of this Count, the "RICO Defendants").

768. The RICO Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the RICO Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

769. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference Paragraphs 324 through 355 concerning the Opioid Diversion Enterprise.

770. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference Paragraphs 365 through 366 concerning the Conduct of the Opioid Diversion Enterprise.

771. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference Paragraphs 367 through 422 concerning the Pattern of Racketeering Activity of the Opioid Diversion Enterprise.

772. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); *United State v. Turkette*, 452 U.S. 576, 580 (1981).

773. The term "enterprise" is defined as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4); Turkette, 452 U.S. at 580; Boyle v. U.S., 556 U.S. 938, 944 (2009). The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section "describes two separate categories of associations that come within the purview of an 'enterprise' -- the first encompassing organizations such as corporations, partnerships, and other 'legal entities,' and the second covering 'any union or group of individuals associated in fact although not a legal entity. '" *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. Id.

774. For over a decade, the RICO Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Defendants

are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the RICO Defendants operated and continue to operate within the "closed-system" created under the Controlled Substances Act, 21 U.S.C. § 821, et seq. (the "CSA"). The CSA restricts the RICO Defendants' ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

775. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from "legitimate channels of trade" to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances]."

776. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined above) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. As discussed in detail below, through the RICO Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA. In doing so, the RICO Defendants

allowed hundreds of millions of pills to enter the illicit market which allowed them to generate obscene profits.

777. Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed in perfect harmony by each of them. In particular, each of the RICO Defendants were associated with, and conducted or participated in, the affairs of the RICO enterprise (defined below and referred to collectively as the "Opioid Diversion Enterprise"), whose purpose was to engage in the unlawful sales of opioids, and deceive the public and federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations. The RICO Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the RICO Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like Plaintiff experienced tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the RICO Defendants' misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for their injuries under 18 U.S.C. § 1964(c).

778. Alternatively, the RICO Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA") is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of

the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because It is a corporation and a legal entity.

779. On information and belief, each of the RICO Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

780. Each of the RICO Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and Manufacturers beyond the RICO Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the RICO Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

781. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association in- fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion enterprise." The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff and the proposed Class members injury in their businesses, as described above in language expressly incorporated herein by reference.

782. Plaintiff's and the proposed Class members' injuries were proximately caused by Defendants' racketeering activities. But for the RICO Defendants' conduct, Plaintiff and the proposed Class members would not have incurred the monetary losses described above and expressly incorporated herein by reference.

783. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff's and the proposed Class members' injury in their businesses, as described above in language expressly incorporated herein by reference.

784. Plaintiff brings this claim against all RICO Defendants. At all relevant times, the RICO Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d) it is unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. 18 U.S.C. § 1962(d).

785. Plaintiff's and the proposed Class members' injuries were directly caused by the RICO Defendants' racketeering activities.

786. Plaintiff seeks actual damages, treble damages, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

COUNT III: NEGLIGENCE

787. Plaintiff, individually and on behalf of the putative Class, realleges and incorporates by reference paragraphs 1-232 and 423-431 as if stated fully herein.

788. Under State law, to establish actionable negligence, one must show the existence of a duty, a breach of that duty, and injury resulting proximately therefrom. All such essential elements exist here.

789. Each Defendant had duties to exercise reasonable, or due, care in marketing, promoting, selling, and distributing highly dangerous Schedule II opioid drugs.

790. Defendants' duties are set out as a matter of law, to monitor, report and prevent against diversion.

791. Each Defendant breached its aforesaid duties by its conduct previously specified herein; namely the false and misleading marketing promotion, sale and distribution of opioid drugs.

792. Manufacturer Defendants breached their duties, as detailed above, when they:

a. misrepresented that opioids improve function;

b. misrepresented that opioids are safe and effective for long-term use;

c. concealed the link between long-term use of opioids and addiction;

d. misrepresented that addiction risk can be managed;

e. masked the signs of addiction by calling them "pseudoaddiction";

f. falsely claimed withdrawal is easily managed;

g. misrepresented or omitted the greater dangers from higher doses of opioids;

h. deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs; and

i. failing to monitor, report, and halt suspicious orders of opioids based on chargeback data.

793. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.

794. Each Defendant owed its aforesaid duties to Plaintiff and the members of the proposed Class because the injuries alleged herein were foreseeable by the Defendants.

795. The fact that Plaintiff and the class he seeks to represent would incur damages including 1) having to provide increased medical services for opioid addicted patients that was unreimbursed and underreimbursed, 2) additional training, 3) negatively impacted patient satisfaction surveys, 4) lost opportunity costs, 4) other damages as indicated and incorporated herein, was both the foreseeable and intended consequence of Defendants' marketing scheme. Defendants set out to change the medical and general consensus supporting chronic opioid therapy, encouraging doctors to prescribe, long- term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

796. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the opioid epidemic would result in a corresponding epidemic of patients with opioid conditions at emergency rooms. It was also foreseeable to Defendants that Plaintiff and the Class members would suffer the aforesaid monetary and other damages. Because of the opioid epidemic, since independent emergency room physicians typically are not reimbursed for their treatment of uninsured patients and receive only partial reimbursement for their treatment of patients with health insurance or government assistance and are not able to receive supplemental compensation (like Hospitals) from the government. Also by treating these patient's independent emergency room physicians suffered lost opportunity cost damages, incurred expenses for

additional training, and suffered emotional distress, reputational harm and upon information and believe lost work, sue to low patient satisfaction survey numbers they were unable to refute.

797. The damages Plaintiff and the Class members incurred but for the opioid epidemic created and engineered by Defendants. Accordingly, Plaintiff's and the Class members' aforesaid damages are the direct and proximate result of Defendants' acts and omissions previously specified herein.

798. Plaintiff and the members of the proposed Class seek compensatory damages for their monetary losses previously specified herein, plus interest and the costs of this action.

COUNT IV: WANTONNESS, RECKLESSNESS, AND GROSS NEGLIGENCE

799. Plaintiff, individually and on behalf of the putative Class, realleges and incorporates by reference paragraphs 1-232 and 423-431 as if stated fully herein.

800. Defendants' aforesaid acts and omissions were done and committed knowing that injury to Plaintiff and the Class members would likely or probably result; were done or committed with a reckless or conscious disregard of the rights of Plaintiff and the Class members; were done or committed without the exercise of even a slight degree of care; were done or committed with conscious indifference to the consequences; and/or constituted a substantial deviation from the standard of care applicable.

801. Each Defendant had duties to exercise reasonable, or due, care in marketing, promoting, selling, and distributing highly dangerous Schedule II opioid drugs.

802. Defendants' duties are set out as a matter of law, to monitor, report and prevent against diversion.

803. Each Defendant breached its aforesaid duties by its conduct previously specified herein; namely the false and misleading marketing promotion, sale and distribution of opioid drugs.

804. Manufacturer Defendants breached their duties, as detailed above, when they:

a. misrepresented that opioids improve function;

b. misrepresented that opioids are safe and effective for long-term use;

c. concealed the link between long-term use of opioids and addiction;

d. misrepresented that addiction risk can be managed;

e. masked the signs of addiction by calling them "pseudoaddiction";

f. falsely claimed withdrawal is easily managed;

g. misrepresented or omitted the greater dangers from higher doses of opioids;

h. deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs; and

i. failing to monitor, report, and halt suspicious orders of opioids based on chargeback data.

805. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.

806. Each Defendant owed its aforesaid duties to Plaintiff and the members of the proposed Class because the injuries alleged herein were foreseeable by the Defendants.

807. The fact that Plaintiff and the class he seeks to represent would have to provide medical services for opioid addicted patients, would have to incur additional training and that these "pill seekers" would negatively rate physicians that refused to provide them opioids, was both the foreseeable and intended consequence of Defendants' marketing scheme. Defendants set out to change the medical and general consensus supporting chronic opioid therapy, encouraging doctors to prescribe, long- term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

808. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the opioid epidemic would result in a corresponding epidemic of patients with opioid conditions at emergency rooms. It was also foreseeable to Defendants that Plaintiff and the Class members would suffer the aforesaid monetary losses and damages because of the opioid epidemic.

809. Plaintiff and the Class members incur partial monetary losses for patients with health insurance, and total monetary losses for uninsured patients, in the treatment of patients with opioid conditions. These patients would not have presented to Plaintiff and the Class members, and would not have had opioid conditions, but for the opioid epidemic created and engineered by Defendants. Accordingly, Plaintiff's and the Class members' aforesaid monetary losses are the direct and proximate result of Defendants' acts and omissions previously specified herein. Plaintiff and Class members also incurred other damages as identified above and incorporated herein.

810. As a direct and proximate result of Defendants' wantonness, recklessness, or gross negligence, Plaintiff and the Class members were monetarily damaged as aforesaid.

811. Plaintiff seeks compensatory and punitive damages, plus the costs of this action.

COUNT V: COMMON LAW FRAUD

812. Plaintiff, individually and on behalf of the putative Class, realleges and incorporates by reference paragraphs 1-232 and 423-431 as if stated fully herein.

813. As alleged herein, Manufacturer Defendants intentionally made false representations and concealed material facts about opioids, including but not limited to:

a. misrepresented that opioids improve function;

b. misrepresented that opioids are safe and effective for long-term use;

c. concealed the link between long-term use of opioids and addiction;

d. misrepresented that addiction risk can be managed;

e. masked the signs of addiction by calling them "pseudoaddiction";

f. falsely claimed withdrawal is easily managed;

g. misrepresented or omitted the greater dangers from higher doses of opioids;

h. and deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs.

814. Manufacturer Defendants made misrepresentations and failed to disclose material facts to physicians and consumers throughout the United States, to induce the physicians to prescribe and administer, and consumers to purchase and consume, opioids as set forth herein.

815. The Distributor Defendants refuse to abide by the duties imposed by federal law which are required to legally acquire and maintain a license to distribute prescription opiates. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities.

816. Distributor Defendants made misrepresentations and failed to disclose material facts to authorities throughout the United States, to induce the prescription, administration and consumption of opioids as set forth herein.

817. Defendants' false representations and omissions were material, and were made and omitted intentionally or recklessly.

818. Defendants intended that physicians and consumers would rely upon their misrepresentations and omissions.

819. Physicians and consumers reasonably relied on Defendants' misrepresentations and omissions. Physicians prescribed and administered, and consumers purchased and consumed, opioids as set forth herein.

820. Because of physicians' and consumers' reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff and the Class members have suffered monetary damages as aforesaid. Plaintiff seeks compensatory and punitive damages, plus the costs of this action.

821. Defendants’ marketing of opioids caused Plaintiff and the putative class he seeks to represent to diagnose, care for and treat opioid addicted patients who presented with opioid

addicted symptoms. All of these medical services provided by Plaintiff were caused by Defendants' fraudulent marketing and scheme. Defendants should be held responsible for all economic damages suffered by Plaintiff and the putative class he seeks to represent. Plaintiff is obligated to cover medically necessary and reasonably required care; he had no choice but to provide these services although often he was not paid or was paid substantially less than market rates.

822. The fact that Plaintiff and the class he seeks to represent would have to provide medical services for opioid addicted patients was both the foreseeable and intended consequence of Defendants' fraudulent marketing scheme. Defendants set out to change the medical and general consensus supporting chronic opioid therapy with the intention of encouraging doctors to prescribe, long- term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

823. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the opioid epidemic would result in a corresponding epidemic of patients with opioid conditions in emergency rooms. It was also foreseeable to Defendants that Plaintiff and the Class members would suffer the aforesaid monetary losses and other damages because of the opioid epidemic. And by treating these patients independent emergency room physicians suffered lost opportunity cost damages

824. Defendants' misrepresentations were material to, and influenced, the opioid-addicted patients presented to Plaintiff and the class he seeks to represent. In the first instance, Plaintiff would not have been presented with, or required to diagnose, care and treat these opioid-addicted patients, but for Defendants' fraudulent and deceptive marketing. Second, Plaintiff has

demonstrated that Defendants' marketing is material by setting forth in detail Defendants' wrongful acts.

825. Plaintiff and the members of the proposed Class seek compensatory damages for their monetary losses previously specified herein, plus interest and the costs of this action.

COUNT VI: NUISANCE

826. Plaintiff, individually and on behalf of the putative Class, realleges and incorporates by reference paragraphs 1-232 and 423-431 as if stated fully herein.

829. The nuisance is the over-saturation of opioids in the patient population of Plaintiff and in the geographic area served by Plaintiff for illegitimate purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use.

830. Defendants' misrepresentations and omissions regarding opioids as set forth above endanger or injure the property, health, safety and comfort of persons in Plaintiffs treatment population and have created opioid addiction in that population which created a nuisance

831. All Defendants substantially participated in nuisance-causing activities.

832. Defendants' nuisance-causing activities include selling or facilitating the sale of prescription opioids to the patients of Plaintiff, as well as to unintended users, including children, people at risk of overdose or suicide, and criminals.

833. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

834. Defendants' activities unreasonably interfere with the economic rights of Plaintiff.

835. The Defendants' interference with these rights of Plaintiff is unreasonable because it:

a. Has harmed and will continue to harm the public health services of and public peace of Plaintiff;

b. Has harmed and will continue to harm the communities and neighborhoods which Plaintiff serves;

c. Is proscribed by statutes and regulation, including the CSA, and the consumer protection statute;

d. Is of a continuing nature and it has produced long-lasting effects;

e. Defendants have reason to know their conduct has a significant effect upon Plaintiff; and

f. Has inflicted substantial costs on Plaintiff.

836. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within families and entire communities. It has created a public health crisis.

837. The resources of Plaintiff are being unreasonably consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources needed in other health care areas.

838. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever.

There is no legitimately recognized societal interest in facilitating widespread opioid addiction and failing to identify, halt, and report suspicious opioid transactions.

839. At all times, all Defendants possessed the right and ability to control the nuisance causing outflow of opioids from pharmacy locations or other points of sale. Distributor Defendants had the power to shut off the supply of illicit opioids to Plaintiff and in the geographic area served by Plaintiff. Despite this Defendants did not abate the nuisance they created.

840. As a direct and proximate result of the nuisance, Plaintiff has sustained economic harm caused by Defendants' nuisance-causing activity, including, but not limited to, non reimburse and under reimbursed costs of providing medical services and treatment, increased training costs, reputational harm, in some cases lost employment, and lost opportunity costs described herein. In short, the Defendants created a mess, leaving it to the Plaintiff and other Independent Emergency Room Physicians the costs of cleaning it up.

841. As a result of Defendants' actions, Plaintiff has suffered a special injury, different from that suffered by the public at large by individual users and by governmental entities, namely that Plaintiff has provided uncompensated care for patients suffering from opioid related conditions.

842. The effects of the nuisance can be abated, and the further occurrence of such harm and inconvenience can be prevented. All Defendants share in the responsibility for doing so.

843. Defendants should be required to pay the expenses Plaintiff has incurred or will incur in the future to fully abate the nuisance.

COUNT VII: UNJUST ENRICHMENT

844. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 874 of this Complaint, as though fully set forth herein.

845. Plaintiff provided unreimbursed healthcare treatment to patients with opioid conditions that Defendants are responsible for creating. Plaintiff thereby conferred a benefit on Defendants because Defendants should bear the expense of treating these patients' opioid conditions. This is because Defendants created the opioid epidemic and the patients' opioid conditions, as described above.

846. Defendants appreciated and knew of this benefit because they knew their opioid promotional and marketing policies would cause, and in fact caused, Independent Emergency Room Physicians throughout the United States to provide unreimbursed healthcare treatment to patients with opioid conditions that Defendants were responsible for creating.

847. The circumstances under which Defendants accepted or retained the benefit, described above, were such as to make it inequitable for Defendants to retain the benefit without payment of its value.

848. As described above, the benefit was received and retained under such circumstances that it would be inequitable and unconscionable to permit Defendants to avoid payment therefor.

849. Defendants have therefore been unjustly enriched.

850. By reason of the foregoing, Defendants must disgorge their unjustly acquired profits and other monetary benefits resulting from its unlawful conduct and provide restitution to the Plaintiff.

COUNT VIII: NEGLIGENCE COMMON LAW FAILURE TO WARN

851. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 874 of this Complaint, as though fully set forth herein.

852. Court VIII is brought by Plaintiff on behalf of himself and the putative class.

853. Manufacturing Defendants knew that opioids were highly addictive and inappropriate and unsafe for the treatment of chronic pain. Manufacturing Defendants had such actual and unequal knowledge of the risks and harms likely to result from the long-term prescription and knew or should have known that harm would result from such use.

854. To expand the market for opioids, however, Manufacturing Defendants engaged in a misinformation campaign to alter public perception of opioids, and deceive doctors, federal regulators, and the public about their addictive and unsafe qualities. Manufacturing Defendants perpetrated virtually uniform misrepresentations, concealments, and material omissions regarding (a) the safety and efficacy of opioids for the treatment of chronic pain and (b) their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

855. Because of barriers to prescribing opioids associated with their regulation as controlled substances, Manufacturing Defendants knew doctors would not treat patients with common chronic pain complaints with opioids, and insurers and other third-party payors would not cover such treatment, unless they were persuaded that opioids had real benefits and minimal risks.

856. Accordingly, Manufacturing Defendants spent millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids while overstating the benefit of using them for chronic pain.

857. Manufacturing Defendants did not disclose to prescribers, patients, third-party payors, or the public that evidence in support of their promotional claims was inconclusive, non-existent, or unavailable, though providing such warnings and accurate information would not have imposed a burden. Rather, each Manufacturing Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence. Defendants' failed to warn doctors of dangers of opioids.

858. Manufacturing Defendants' misinformation campaign was intended to and did encourage patients to ask for, doctors to prescribe, and payors to pay for chronic opioid therapy.

859. Plaintiff and the Class thus, both directly and indirectly, relied on the representations as to the efficacy and safety of opioid drugs for the treatment of chronic pain as promoted by Defendants. Because Defendants controlled all knowledge of the tests upon which the claims of opioid drugs' efficacy and safety were based, Plaintiff and the Class, as well as other third-party payors and members of the medical community and public, were obligated to rely on Defendants' representations about opioids. Further, Defendants perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about the use of opioids for chronic pain and ensure that they were authorized for coverage and broadly distributed.

860. Manufacturing Defendants knew of widespread prescription opioid addiction and abuse, and diversion to illegal channels, including through their financial incentives and information sharing arrangements with other Defendants. Manufacturing Defendants also

knew that the dangerous qualities of opioids bore a direct relationship to the volume of opioids being ordered, authorized, and prescribed. Manufacturing Defendants further knew that widespread opioid addiction and abuse was harmful to the individuals consuming opioids, their friends, families, and communities, and those, like Plaintiff, responsible for treating patients with opioid misuse associated with opioid addiction and abuse among their insureds.

861. Nonetheless, Manufacturing Defendants unreasonably persisted in spreading misinformation and burying the truth about the safety and efficacy of opioids. In doing so, Manufacturing Defendants failed to take reasonable precautions in presenting opioids to the public.

862. By failing to adequately warn the public, including prescribing doctors, and Plaintiff,

of the dangers of opioids, Manufacturing Defendants' conduct directly injured Plaintiff and the Class.

863. As a consequence of the Manufacturing Defendants' breach of their common law duty to warn, Plaintiff and the Class have suffered damages and will continue to suffer damages.

COUNT IX: VIOLATION OF SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT § 39-5-140 et. seq.

864. Plaintiff repeats, realleges, and incorporates by reference the allegations set forth in Paragraphs 1 through 874 of this Complaint, as though fully set forth herein and is brought against all Defendants

865. This cause of action is brought pursuant to South Carolina § 39-5-10 to -560. which is known as the Unfair Trade Practices Act (UTPA).

866. The intent of the UTPA is to provide recourse when there is an unfair or deceptive act or practice in the conduct of any trade or commerce which injuriously affects the people of South Carolina.

867. Section 39-5-140(a) creates a private right of action in favor of "[a]ny person who suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of an unfair or deceptive method, act or practice declared unlawful by § 39-5-20.

868. Plaintiff is a “person” within the meaning of § 39-5-10.

869. All Defendants engaged in “[t]rade or commerce” within the meaning of S. C. Code Ann. § 39-5-10(b) (1976).

870. During the relevant period and as detailed further herein, the Marketing Defendants have each engaged in unfair and deceptive acts or practices in commerce in violation of the UTPA by actively promoting and marketing the use of opioids for indications not federally approved, circulating false and misleading information concerning opioids’ safety and efficacy, and downplaying or omitting the risk of addiction arising from their use.

871. Each of the Defendants have engaged in unfair and/or deceptive trade practices by omitting the material fact of its failure to design and operate a system to disclose suspicious orders of controlled substances, as well as by failing to actually disclose such suspicious orders, as required of “registrants” by the federal CSA, 21 C.F.R. § 1301.74(b). The CSA defines “registrant” as any person who is registered pursuant to 21 U.S.C § 823. 21 C.F.R. § 1300.02(b). Section 823(a)-(b) requires manufacturers and distributors of controlled substances Schedule II to register.

872. Defendants' unfair or deceptive acts or practices in violation of the UTPA negatively affected the public interest, and are immoral, unethical, oppressive and unscrupulous, as well as malicious, wanton and manifesting of ill will.

873. Defendants' actions were willful and knowing violations of the UTPA § 39-5-20.

874. As a direct and proximate result of Defendants' violations of the UTPA, Plaintiff has suffered and continues to suffer injury-in-fact and actual damages as identified herein and incorporated by reference.

876. Defendants, individually and acting through acting through their employees and agents, and in concert with each other, knowingly advertised and made material misrepresentations and omissions of facts to Plaintiff and the putative class to induce Plaintiff and the punitive class to prescribe and have patients purchase, administer, and consume opioids as set forth in detail above.

877. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

878. Defendants intended that Plaintiff, physicians, patients, and/or others would rely on their misrepresentations and omissions.

879. Plaintiff, physicians, patients, and/or others reasonably relied upon Defendants' misrepresentations and omissions.

880. In the alternate, the Defendants recklessly disregarded the falsity of their representations regarding opioids.

881. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, Plaintiff and the class, suffered actual pecuniary damage.

882. Defendants' conduct was willful, knowing, wanton, and malicious and was directed at the public generally and violation of the UTPA.

883. Plaintiff is entitled to recover damages caused by Defendants' fraud in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff individually and on behalf of all others similarly situated, ask that the Court:

(a) Certify the Class proposed herein;

(b) Appoint Plaintiff as representative of the Class;

(c) Appoint Plaintiff's counsel as attorney for the Class;

(d) Enter judgment awarding Plaintiff and the Class members monetary damages, compensatory in nature, on their negligence claim;

(e) Enter judgment awarding Plaintiff and the Class members monetary damages, compensatory and punitive, on their claims for wanton, reckless, and grossly negligent conduct, and on their claims for fraud;

(f) Enter judgment awarding Plaintiff and the Class members treble damages on their RICO claims;

(g) Award Plaintiff and the class members prejudgment interest and post-judgment interest as provided by law;

(h) Award Plaintiff and the Class members a reasonable attorney's fee and costs; and

(i) Provide such further relief as may be just and proper.

JURY DEMAND

Plaintiff, individually and on behalf of the Class members, demand a trial by jury on all issues so triable.

Respectfully Submitted,

DATED: August 7, 2024

Dean A. Hayes
Federal Bar # 5917
McCabe, Trotter & Beverly, P.C.
4500 Fort Jackson Blvd., Suite 250
Columbia, SC 29209
Main: (803) 724-5000
Direct: (803) 724-5006
Fax: (803) 724-5001
Email: dean.hayes@mccabetrotter.com

Attorney Paul S. Rothstein
Florida Bar Number: 310123
Attorney Paul S. Rothstein, P.A.
626 N.E. 1st Street
Gainesville, FL 32601
(352) 376-7650
(352) 374-7133
E-Mail: psr@rothsteinforjustice.com